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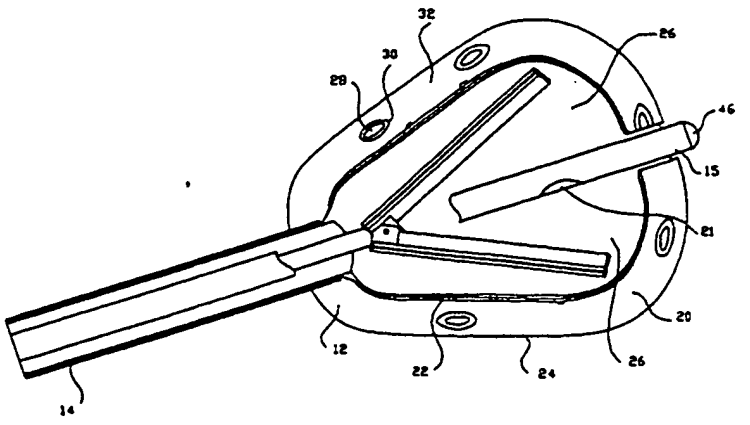
(54) Title: THIN LAYER ABLATION APPARATUS

(57) Abstract

An apparatus for ablating an inner layer in an organ or lumen of a body, or any desired thin layer. The ablation apparatus includes a balloon-like expandable member (12) (the balloon hereinafter) having an interior section for housing an electrolytic solution, a conforming member (20) made of a material such as a resilient foam rubber (the foam rubber hereinafter). Capable of substantially conforming to a portion of the inner layer of the organ. The foam rubber delivering the electrolytic solution housed within the balloon to the inner layer of the organ, one or more electrodes (39, 41) positioned in or on the foam rubber for delivering RF energy to the inner layer of the organ, an electrical connector device connecting the one or more electrodes to an RF energy source and an electrolytic solution delivery tube for delivering the electrolytic solution from the electrolytic solution source to the balloon. The apparatus may also include a feedback device which monitors a characteristic of the inner layer and, in response, controls the delivery of RF energy to the one or more electrodes. The one or more electrodes may be positioned in or on the foam rubber for delivering RF energy to the inner layer of the organ, each electrode including an insulator formed on a surface of the electrode. The foam rubber may also include "non"-zone areas with a first porosity rate for delivering electrolytic solution to the inner layer and zone areas for housing an electrode and electrolytic solution, the zone areas having a second porosity rate that is less than the first porosity rate such that the electrolytic solution passes through the zone areas at a slower rate than through the non-zone areas. The ablation apparatus may also include a membrane positioned between the balloon and the foam rubber, the membrane adapted to receive the electrolytic solution from the balloon and deliver the electrolytic solution to the foam rubber.



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THIN LAYER ABLATION APPARATUS

BACKGROUND OF THE INVENTION

Relationship to Copending Application

This application is a continuation of U.S. Patent Application Serial No. 08/319,373 entitled "Thin Layer Ablation Apparatus" by Baker, et al, filed October 6, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/286,862 entitled "Thin Layer Ablation Apparatus" by Edwards, et al, filed August 4, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/272,162 entitled "Thin Layer Ablation Apparatus" by Edwards, et al, filed July 7, 1994, which is a continuation-in-part of U.S. Patent Application Serial No. 08/265,459 entitled "Thin Layer Ablation Apparatus" by Edwards, filed June 24, 1994, all of which are incorporated by reference.

Field of the Invention

This invention relates generally to an ablation apparatus for the selective ablation of the inner layers of body organs or lumens, and more particularly, to an ablation apparatus which includes an expandable member housing a heated electrolytic solution.

Description of Related Art

There are a number of body organs and lumens, including but not limited to the uterus, gall bladder, large intestine and the like, that have inner layers which have abnormal conditions. Traditional methods of treatment have included removal of the body organ to treat the abnormal condition, the use of lasers, and the application of a thermal source.

A diseased condition of the uterus, menorrhagia, is defined as excessive menstrual bleeding in the absence of organic pathology. It has no known aetiology and it has been postulated that it is due to an

inappropriate exposure of the endometrium to hormones. Menorrhagia is an exceedingly common problem, typically comprising approximately one in five outpatient referrals to gynecological departments. Women suffering severe menorrhagia are at risk from chronic anemia. The first treatment employed may be the administration of drug therapy. A major disadvantage is the need to administer drugs long term, and frequently the beneficial effects are only temporary. Another treatment is hysterectomy.

A number of physical and chemical methods have been tried as alternatives to hysterectomy, including the use of superheated steam, cryotherapy, urea injection and radium packing. The most commonly used methods as an alternative to hysterectomy are, ablation of the endometrium either by using a laser, such as a Nd:YAG laser, or the use of RF energy applied with an electrode.

Laser treatments have provided only limited success. RF is an attractive alternative. In RF heating, a conductive probe is placed within the uterine cavity and an insulated ground-plane electrode or belt is placed around the patient's midriff. RF energy is applied to the thermal probe with the external belt electrode acting as the return arm of the circuit. The electrical load presented by the RF thermal probe, patient, and external belt is matched to the output of the RF generator via a tuning unit, to form a series resonant circuit. Once tuned, the majority of the power applied to the probe is deposited into the endometrium as heat.

Current flows primarily capacitively, and an electric field is set up around the active tip of the probe. Tissue lying within the field becomes heated because of rapid oscillation of charged particles and locally induced currents.

Prior, et al. reported on the use of RF to treat menorrhagia. Power at 27 • 12 MHz was delivered to a probe that was placed into the uterine cavity and capacitively coupled to a second electrode consisting of a belt placed around the patient, Prior, et al., Int. J. Hyperthermia, **7:2** 213-220

(1990). The active electrode was a 10 mm diameter stainless-steel cylinder with a length of 70 mm. This method, however, did not adequately deliver RF energy to the entire endometrium. Because the endometrium has an irregular surface, it is difficult to deliver sufficient RF energy to the entire structure to effectively treat menorrhagia.

It is desirable to have close contact between the RF conductive face and the endometrium. In U.S. Patent No. 5,277,201, an electroconductive, expandable balloon is expanded into the interior of the uterus and effects electrical contact with the endometrial lining to be destroyed. The device, however, fails to provide sufficient physical contact with the entire endometrium. As a result, treatment of the endometrial lining is not complete. Not only is the physical contact with the endometrium unsatisfactory, a more effective delivery of RF energy to the endometrium is also needed.

There is a need for an RF ablation apparatus that provides more suitable conformation with a lining of a body organ, such as the endometrium of the uterus. There is also a need for the effective delivery of RF energy to the endometrium as well as other interior layers of body organs.

There is also a need for an ablation device for the endometrium which includes a feedback mechanism that is responsive to detected characteristics of the endometrium, and the delivered RF selectable distributed energy is adjusted in response to the feedback.

There is also need for an ablation device which provides controlled and selectable distributed energy to a selected tissue site, such as the endometrium.

There is also a need for an RF ablation apparatus, with an open foam cell structure surrounding an expandable member, that includes zones of semi-trapped electrolytic solution adjacent to electrodes, with a zone porosity that is less than non-zone sections of the open foam cell

foam where there aren't electrodes. Additionally, there is a need for an ablation device which provides a heated electrolytic solution in the expandable member that is delivered to the inner layer of a body organ or lumen.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide an ablation apparatus suitable for interior thin walled areas of body organs.

Another object of the invention is to provide an ablation apparatus that effectively conforms to the shape of the interior of a body organ.

Yet another object of the invention is to provide an ablation apparatus with the conforming member that effectively conforms to the shape of the interior of a body organ or lumen, and delivers heated electrolytic solution to a target tissue site.

Still a further object of the invention is to provide an ablation apparatus that includes a plurality of electrodes positioned in the conforming member, and heated electrolytic solution is passed from an interior of an expandable member surrounded by the conforming member to the inner lining of an organ or lumen in order to reduce the amount of time required for ablation.

A further object of the invention is to provide an ablation apparatus with expanded electrodes by positioning the electrodes in zones of the conforming member with a lower porosity than non-zone areas of the conforming member. Within the zones are pockets of semi-trapped electrolytic solution that increase the size of the electrode.

Yet another object of the invention is to provide an ablation apparatus that includes a flexible circuit.

Still a further object of the invention is to provide an ablation apparatus that includes an electrode positioned between first and second

fluid conduits that surround an expandable member housing an electrolytic fluid.

Another object of the invention is to provide an ablation apparatus that includes a plurality of electrodes, each with an insulator surrounding a portion of the electrode, to provide for the selectable distribution of RF energy to a desired surface.

Yet another object of the invention is to provide an ablation apparatus that provides selectable delivery of RF energy to a tissue site, and includes a feedback device in response to a detected characteristic of the tissue site.

Still a further object of the invention is to provide an ablation apparatus that evenly distributes energy to the endometrium, and includes a feedback device to monitor impedance and temperature at the endometrium.

Another object of the invention is to provide an ablation apparatus that includes a feedback device in response to a detected characteristic of the endometrium, as well as one or more ultrasound transducers.

Another object of the invention is to provide an ablation apparatus that includes a feedback device for the controlled and selectable delivery of RF energy to the endometrium, where the impedance or a temperature profile of the endometrium is monitored.

A further object of the invention is to provide an ablation apparatus with a feedback device for the selectable delivery of RF energy, where the apparatus includes electrodes with insulators that are formed on a portion of each electrode for the even delivery of RF energy to a selected tissue site.

Still a further object of the invention is to provide an ablation apparatus that releases heated electrolytic solution to the endometrium, selectively distributes energy to the endometrium and includes a feedback device to monitor impedance and temperature at the endometrium.

Still a further object of the invention is to provide an ablation apparatus that includes a feedback device in response to a detected characteristic of the endometrium and the feedback provides a controlled delivery of RF energy to the endometrium.

Another object of the invention is to provide an ablation apparatus including a conforming member made of a foam type substance.

A further object of the invention is to provide an ablation apparatus with a feedback device for the controlled delivery of RF energy, and the apparatus includes a conforming member made of a foam type substance.

Still a further object of the invention is to provide an ablation apparatus that includes a microporous membrane.

Still a further object of the invention is to provide an ablation apparatus with a feedback for the controlled delivery of RF energy where the apparatus includes a microporous membrane.

Still a further object of the invention is to provide an ablation apparatus that positions electrodes with insulators between two foam structures to provide for the selectable distribution of RF energy to a desired tissue site.

Yet another object of the invention is to provide an ablation apparatus that includes a printed circuit.

Still a further object of the invention is to provide an ablation apparatus that includes a printed circuit which monitors impedance, temperature, circuit continuity, and is capable of multiplexing.

Yet another object of the invention is to provide an ablation apparatus with an expandable member, such as a balloon, which houses an electrolytic solution that selectively flows out of an interior of the balloon and is delivered to a desired tissue site.

These and other objects are achieved with an ablation apparatus for ablating an inner layer in an organ or a lumen of the body. The ablation apparatus includes an expandable member having an interior section for

housing an electrolytic solution, a conforming member made of a material capable of substantially conforming to a portion of the inner layer of the organ, the conforming member delivering the electrolytic solution housed within the expandable member to the inner layer of the organ, one or more electrodes positioned in or on the conforming member for delivering RF energy to the inner layer of the organ, an electrical connector device connecting the one or more electrodes to an RF energy source and an electrolytic solution delivery tube for delivering the electrolytic solution from the electrolytic solution source to the expandable member.

The apparatus may also include a feedback device which monitors a characteristic of the inner layer and, in response, controls the delivery of RF energy to the one or more electrodes. The one or more electrodes may be positioned in or on the conforming member for delivering RF energy to the inner layer of the organ, each electrode including an insulator formed on a surface of the electrode. The conforming member may also include non-zone areas with a first porosity rate for delivering electrolytic solution to the inner layer and zone areas for housing an electrode and electrolytic solution, the zone areas having a second porosity rate that is less than the first porosity rate such that the electrolytic solution passes through the zone areas at a slower rate than through the non-zone areas. The apparatus may also include a membrane positioned between the expandable member and the conforming member, the membrane adapted to receive the electrolytic solution from the expandable member and deliver the electrolytic solution to the conforming member.

The expandable member may include a plurality of apertures through which the electrolytic solution flows from the expandable member. The expandable member may also be formed of a nonporous material. The expandable member may be positioned within the conforming member. The expandable member may be expanded mechanically and

may be formed of a nonporous material. The conforming member may be formed of a foam or an insulating material.

The conforming member may be made of an open cell material.

The one or more electrodes may be multiplexed. The one or more electrodes may form a flexible circuit. The one or more electrodes may form a printed circuit that is multiplexed. The printed circuit may include a plurality of segments. The electrodes may be positioned on a support member.

The feedback device may monitor the impedance or temperature of the inner layer at a portion of the inner layer. The feedback device can include a controller and/or a multiplexer.

In one embodiment of the invention, the ablation apparatus includes an expandable member, made of a material with a porous exterior surface. A heated electrolytic solution is housed in an interior of the expandable member and is released through the porous exterior surface. A conforming member, with a conductive surface, and a back side in a surrounding relationship to the expandable member, is made of a material that provides substantial conformity between the conductive surface and the inner layer of the organ or lumen. Heated electrolytic solution is received from the interior of the expandable member, and delivered through the fluid conduit to the inner layer. A plurality of electrodes are positioned between the expandable member and the fluid conduit. An RF power source is coupled to the plurality of electrodes. Also included is a device for heating the electrolytic solution to a selected temperature.

The conforming member, also called a fluid conduit, is made of an open cell material. The zone areas have less open cells than the non-zone areas. Electrolytic solution in the zones, and the associated electrodes, effectively form larger electrodes. Two pieces of open cell foam can be sealed together to form the conforming member, with one or more electrodes positioned between the two pieces. Sealing of the two pieces

of open cell foam can be in the non-zone areas. Alternatively, the two pieces can sealed in the zone areas, and around the periphery of the conforming member. A groundpad can be attached to an exterior surface of a patient.

The ablation apparatus can also include an electrolytic solution source, and a fluid delivery device for delivering the electrolytic solution from the electrolytic solution source to the interior of the expandable member. A device for heating the electrolytic solution can be associated with the electrolytic solution source. In this embodiment, heated electrolytic solution is introduced into the interior of the expandable member. Alternatively, the device for heating the electrolytic solution can be positioned in the interior of the expandable member. Additionally, a feedback device can be included that is responsive to a detected characteristic of the inner layer and provides a controlled delivery of RF energy to the plurality of electrodes.

In an alternate embodiment, the conforming member is formed of a first and a second fluid conduit surrounding the expandable member. According to this embodiment, the first fluid conduit surrounds the exterior of the expandable member. The first fluid conduit provides delivery of electrolytic solution from the expandable member. A second fluid conduit surrounds the first fluid conduit. The second conduit is made of a material that provides substantial conformity between the conductive surface and a shape of the inner layer of the organ. The second fluid conduit delivers electrolytic solution from the first fluid conduit to the inner layer. A plurality of electrodes are positioned between the first and second conduits. By positioning the electrodes between the first and second fluid conduits, energy delivery from the electrodes to the inner layer is selectable. It is selectable in that the energy can be distributed evenly over the target surface, and energy delivery can be variable, depending on the condition of the selected tissue site.

The electrodes can be positioned on a support member. Additionally, the electrodes can form a flexible circuit made of a plurality of segments. The electrodes can be a printed circuit, or a plurality of individual electrodes. The expandable member can be expanded within the interior of a selected organ mechanically, or by introducing a fluid, such as an electrolytic solution, into its interior. In one embodiment, the expandable member is a balloon.

The first fluid conduit can be made of a foam. The second fluid conduit is made of a material that provides substantial conformity between the conductive surface and the inner layer of the organ being ablated. The second fluid conduit is preferably made of a foam.

In one embodiment, the second fluid conduit has non-zone sections with a second rate of porosity for delivering electrolytic solution to the inner layer. The second fluid conduit also includes zones for housing the electrodes and electrolytic solution. The zones, with the electrodes, have a second porosity rate that is less than the first porosity rate, and electrolytic solution passes through the zone at a slower rate than electrolytic solution passing through non-zone areas of the conforming member. The second fluid conduit has an RF conductive surface and a back side in surrounding relationship to the exterior surface of the expandable member. An RF power source is coupled to the electrode.

In another embodiment of the invention, the ablation apparatus includes an expandable member, made of a material with a porous exterior surface. A heated electrolytic solution is housed in an interior of the expandable member and is released through the porous exterior surface. A fluid conduit, with a conductive surface, and a back side in a surrounding relationship to the expandable member, is made of a material that provides substantial conformity between the conductive surface and the inner layer of the organ or lumen. Heated electrolytic solution is received from the interior of the expandable member, and delivered through the fluid conduit

to the inner layer. A plurality of electrodes are positioned between the expandable member and the fluid conduit. An RF power source is coupled to the plurality of electrodes. Also included is a device for heating the electrolytic solution to a selected temperature.

The fluid conduit can be made of an open cell material. The zone areas have less open cells than the non-zone areas. Electrolytic solution in the zones, and the associated electrodes, effectively form larger electrodes. Two pieces of open cell foam can be sealed together to form the conforming member, with one or more electrodes positioned between the two pieces. Sealing of the two pieces of open cell foam can be in the non-zone areas. Alternatively, the two pieces can sealed in the zone areas, and around the periphery of the conforming member. A groundpad can be attached to an exterior surface of a patient.

The ablation apparatus can also include an electrolytic solution source, and a fluid delivery device for delivering the electrolytic solution from the electrolytic solution source to the interior of the expandable member. A device for heating the electrolytic solution can be associated with the electrolytic solution source. In this embodiment, heated electrolytic solution is introduced into the interior of the expandable member. Alternatively, the device for heating the electrolytic solution can be positioned in the interior of the expandable member.

Optionally, a feedback device can be included that is responsive to a detected characteristic of the inner layer and provides a controlled delivery of RF energy to the plurality of electrodes. In response to the detected characteristics, the ablation device then provides a controlled delivery of RF energy to the electrodes or segments of the circuit. Various detected characteristics include, impedance of a segment of the inner layer, and a temperature profile of the inner layer at a segment. The feedback device can include a controller and a multiplexer. With the

multiplexer, individual electrodes or flexible circuit segments are multiplexed.

In one embodiment, the expandable member is a balloon, and the first and second conduits are made of an open cell foam. Additionally, the foam material of the conforming member is particularly pliable and suitable for conforming to the inner layer, and achieves an effective ablation of all or a part of the inner layer even when the inner layer has a very irregular surface.

The feedback device may be used to detect impedance or a temperature profile of the inner layer at the electrodes or a segment of the circuit. The amount of delivered RF energy may be adjusted according to the detected impedance or temperature profile. Additionally included in the conforming member is one or more ultrasound transducers.

The conforming member provides a conductive surface that conforms to surfaces that have irregular shapes and with the feedback device, a controlled delivery of RF energy is delivered to the endometrium. The combinations of partially insulated electrodes positioned between the two fluid conduits provides for a selectable, even, non-direct delivery of RF energy. Thus, RF energy can be effectively delivered to irregular surfaces. The feedback device provides controlled delivery of RF energy based on detected characteristics of the endometrium. The ablation apparatus is multiplexed between different electrodes or circuit segments of the flexible circuit.

The flow rate of electrolytic solution leaving the balloon, including but not limited to saline solution, may be adjusted and depends on the pressure applied by the electrolytic solution to the balloon, typically caused by increasing or decreasing the amount of electrolytic solution in the balloon. The membrane is microporous, and the conforming member, which typically is a layer of a foam type material, both provide a controlled flow of electrolytic solution to the inner wall of the body organ. Additionally,

the foam material of the conforming member is particularly pliable and suitable for conforming to the inner wall, and achieves an effective ablation of all or a part of the inner wall even when it has a very irregular surface.

The ablation apparatus of the invention is suitable for ablating a variety of surfaces of body organs including but not limited to the endometrium of the uterus.

DESCRIPTION OF THE DRAWINGS

Figure 1(a) is a perspective view of an ablation apparatus of the invention housed in an introducer sleeve and includes viewing optics.

Figure 1(b) is a perspective view of an ablation apparatus of the invention in a non-deployed position as the introducer sleeve is withdrawn.

Figure 1(c) is a perspective view of an ablation apparatus of the invention in a deployed position.

Figure 2 is a perspective view of a handle associated with the ablation apparatus of the invention.

Figure 3 is a representative block diagram of the invention showing the light, RF, ultrasound and electrolytic sources and their relationships to the expandable member.

Figure 4 is a flow chart listing the operation of the ablation apparatus of the invention.

Figure 5(a) is a cross-sectional view of the ablation apparatus of the invention, illustrating the zone and non-zone sections of the conforming member.

Figure 5(b) is a cross-sectional view of the ablation apparatus of the invention with an expandable device surrounded by a conforming member.

Figure 5(c) is a perspective view of the ablative effect of electrodes positioned on a balloon without an insulator.

Figure 5(d) is a cross-sectional view of the ablation apparatus of the invention with a porous membrane positioned between one side of an

expandable device and a conforming foam structure that is positioned adjacent to an inner layer of an organ.

Figure 5(e) is a cross-section view of an ablation apparatus of the invention and includes a core lumen that houses illumination and viewing optical fibers, fluid conduits and sensor and electronic cabling.

Figure 6(a) is a cross-sectional view of the conforming member made of an open cell foam material. Two pieces of foam are sealed to create a zone, or pocket, of electrolytic solution around an RF electrode.

Figure 6(b) is a cross-sectional view of the conforming member made of an open cell foam material. Two pieces of foam are sealed at the electrode, creating a zone that comprises an RF electrode and electrolytic solution which remains in the zone a longer time than the electrolytic solution in non-zone regions of the conforming member.

Figure 6(c) is a cross-sectional view of two layers of an open cell foam that are jointed with an RF electrode disposed between the two layers, forming a zone. The zone has a lower porosity rate than non-zone areas. Included in the zone is electrolytic solution, which together with the RF electrode create a larger electrode.

Figure 7 is a graph and table of measured temperatures of zone and adjacent non-zone sections of the ablation apparatus illustrated in Figure 6(a)

Figure 8 is a graph and table of measured temperatures of zone and adjacent non-zone sections of the ablation apparatus illustrated in Figure 6(b).

Figure 9 is a cross-sectional view of a multiplicity of zones in the conforming member.

Figure 10 is a perspective view of a plurality of electrodes that comprise a flexible circuit in the interior of the conforming member.

Figure 11 is a perspective view of the ablation apparatus of the invention, with the flexible circuit positioned adjacent to an interior side of

the conforming member. In this figure, the insulator has been removed for ease of viewing the flexible circuit.

Figure 12 is a cross-section view of the ablation apparatus of the invention, with the flexible or printed circuit positioned adjacent to an interior side of the conforming member, a plurality of conductive filaments being disposed in the conforming member.

Figure 13 is a perspective view of one of the segments of the flexible circuit shown in Figure 9.

Figure 14 is a cross-sectional view of the introducer sheath associated with the expandable member of the invention. Housed in the introducer sheath are viewing and illumination fibers, a tension wire, an RF cable, an ultrasound cable and an electrolytic solution tube.

Figure 15 is a cross-sectional diagram illustrating the relative positioning of the flexible circuit of the invention in the uterus.

Figure 16 is a block diagram of an ablation apparatus of the invention that includes a controller and multiplexer.

Figure 17 is a block diagram of one embodiment of a system for processing outputs from the temperature sensors and ultrasound transducers.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

An ablation apparatus 10 of the invention is illustrated in Figures 1(a), 1(b) and 1(c) and includes an expandable member 12 that is introduced into a desired body organ or lumen through an introducer sleeve 14 which can be attached to a handpiece such as the handpiece 16 illustrated in Figure 2. In one embodiment of the invention, expandable member 12 is a balloon, but it will be appreciated that other devices capable of being in confined non-deployed states, during their introduction into the desired body organ or lumen, and thereafter expanded to deployed states, can be utilized.

Expandable member 12 is rolled or folded around a core lumen 15 which can contain optics, fluid paths, sensor and electronic cabling. It can be attached to a ratchet hinge 18 which imparts movement of expandable member 12 when it is in a body organ or lumen. Ablation apparatus 10 can generally be rolled or folded around a helical type of elongated structure in order to provide a wringing type of motion to assist in its removal from the body organ or lumen.

Expandable member 12 is introduced through introducer sleeve 14 in a folded, or non-distended configuration. Introducer sleeve 14 can be of different cross-sectional sizes. In one embodiment, it is small enough to be introduced into the cervix under local anaesthesia, and can be on the order of about 5 mm or less in diameter.

Formed spring wires can be included in expandable member 12 to assist in opening it to the deployed position. Positioned on core lumen 15 are a variety of actuators which provide physician control of ablation apparatus 10, as more fully described hereafter. The actuators can be rocker switches, slider switches and the like, as are well known to those skilled in the art. Ablation apparatus 10 is sufficiently opaque that it is visible under ultrasound.

Introducer sleeve 14 is introduced into the desired organ or body lumen, as shown in Figure 1(a), with expandable member 12 in a non-deployed configuration. Following introduction, introducer sleeve 14 is withdrawn and can be retracted into core lumen 15. Introducer sleeve 14 can be of conventional design, such as an introducing catheter, well known to those skilled in the art. Expandable member 12 can be swept from side to side, which movement can be imparted by hinge 18. Hinge 18 also provides for easy introduction of ablation apparatus 10 through the vagina, and into the cervix and uterus.

Generally, ablation apparatus 10 can be a monopolar or bipolar electrode system. It is capable of expanding so that expandable member

12 becomes expanded within a selected body organ or lumen, and RF energy is delivered to an inner lining of the organ or lumen. RF and thermal energy are passed through the inner lining or surface for a time period selected that is sufficient to achieve a desired level of ablation. This varies depending on the body organ or lumen. In a monopolar mode RF current flows through body tissue from a return electrode, in the form of a conductive pad, applied to the patient's outer skin. Maximum heating occurs where the current density is the greatest.

In one embodiment of the invention, the body organ is the uterus, and the lining is the endometrium. It will be appreciated that the present invention is not limited to the endometrium of the uterus and that other organs, including but not limited to the general field of gynecology, can also be treated with the invention.

Electric current flowing through the endometrium causes heating due to resistance of the tissue. Endometrial ablation can be accomplished as a relatively simple medical procedure with local anesthesia.

Referring now to Figures 2 and 3, a rocker switch 60 operates the rotation and viewing of viewing optics 46, as well as the movement of the flexible scope. A slider switch 62 controls movement of introducer sleeve 14. Rocker switch 64 is associated with tension wire 48. It is activated to cause hinge 18 to pivot and impart mechanical movement to expandable member 12. Rocker switch 66 is operated by the physician to control the delivery, and in certain instances, the amount of RF energy from a suitable RF energy source 68. Rocker switch 70 controls the flow of electrolytic solution to and from expandable member 12 to an electrolytic solution source 72. Finally, a switch 74 is associated with ultrasound transducers 58. It will be appreciated that a video camera system can be associated with handle 16.

Further with regard to Figure 3, an optical system 76 can include a light source, associated illumination and imaging fibers 44, which can be

in the form of a flexible endoscope, and associated switch 60 that operates the rotation and viewing of viewing optics 46. Optical system 76 can also include an output going to a VCR, camera, and the like, and a feedback output to RF source 68 and a controller 78. RF energy source 68 can incorporate a controller, as well as both temperature and impedance monitoring devices.

Also included may be an electrolytic solution source 72 with a pump/pressure flow control device 80, as is well known to those skilled in the art. Also included may be a heating device 82, for heating the electrolytic solution, is associated with electrolytic solution source 72, or it can be positioned in expandable member 12. Suitable heating devices include but are not limited to coils, bipolar electrodes, catalysts, and other devices, as are well known to those skilled in the art. An ultrasound source 84 may also be coupled to one or more ultrasound transducers 58 that are positioned in or on conforming member 20. Ultrasound transducers 58 can be positioned apart from conforming member 20. An output is associated with ultrasound source 84 and RF energy source 68.

Each ultrasound transducer 58 can include a piezoelectric crystal mounted on a backing material. An ultrasound lens, fabricated on an electrically insulating material, is mounted between the piezoelectric crystal and conforming member 20. The piezoelectric crystal is connected by electrical leads 54 to ultrasound power source 86. Each ultrasound transducer 58 transmits ultrasound energy through conforming member 20 into adjacent tissue. Ultrasound transducers 58 can be in the form of an imaging probe such as Model 21362, manufactured and sold by Hewlett Packard Company, Palo Alto, California.

Figure 4 is a flow chart illustrating one embodiment of the operation of ablation apparatus 10. In this embodiment, ablation apparatus 10 is first introduced into the uterus under local anaesthesia. Introducer sleeve 14 is then withdrawn, and expandable member 12 is expanded, either

mechanically, with the introduction of a fluid or gaseous expanding medium, such as an electrolytic solution, or a combination of both. For this purpose formed spring wires can be used alone or in combination with a fluid to expand expandable member 12. Electrolytic solution is introduced into expandable member 12, causing it to become distended and be self-retained in the uterus.

Electrolytic solution in expandable member 12 is heated to a pre-selected temperature, which can be modified and adjusted as necessary. For example, electrolytic solution can be heated and maintained at a temperature between about 60 to 90 degrees C. It can be initially introduced into expandable member 12 at the higher temperature, or it can be heated to the higher temperature in expandable member 12. By providing a heated electrolytic solution, there is a reduction in the amount of time needed to complete a satisfactory ablation.

The diagnostic phase then begins. This is achieved through a variety of mechanisms, including but not limited to, (i) visualization, (ii) measuring impedance to determine the electrical conductivity between the endometrium and ablation device 10 and (iii) the use of ultrasound imaging to establish a base line for the tissue to be treated.

In the treatment phase, the ablation of the uterus can be conducted under feedback control. This enables ablation device 10 to be positioned and retained in the uterus. Treatment can occur with minimal attention by the physician. Ablation apparatus 10 automatically conforms to the interior of the uterus, provides a relatively even flow of heated electrolytic solution to assist in the ablation, and a plurality of electrodes contained in zones, effectively create a flexible circuit. It can be multiplexed in order to treat the entire endometrium or only a portion. Feedback can be included and is achieved by, (i) visualization, (ii) impedance, (iii) ultra-sound or (iv) temperature measurement. The feedback mechanism permits the turning on and off of different electrodes of the flexible circuit in a desired ablative

pattern, which can be sequential from one electrode to the next, or it can jump around different electrodes.

The amount of ablation can vary. However, it is desirable to ablate about 2 to 3 mm, with approximately 1 mm of the myometrium. Ultrasound can be used to create a map of the interior of the uterus. This information is input to a controller. Individual electrodes are multiplexed and volumetrically controlled. If desired, the area of ablation can be substantially the same for each ablation event.

Even though there are folds and crevices in the endometrium, the entire endometrium can be treated and selectively ablated. The selective ablation may be the even penetration of RF energy to the entire endometrium, a portion of it, or applying different levels of RF energy to different endometrium sites, depending on the condition of the endometrium. The depth of RF and thermal energy penetration in the endometrium is controlled and selectable.

A second diagnostic phase may be included after the treatment is completed. This provides an indication of ablation treatment success, and whether or not a second phase of treatment, to all or only a portion of the uterus, now or at some later time, should be conducted. The second diagnostic phase is accomplished through, (i) visualization, (ii) measuring impedance, (iii) ultrasound or (iv) temperature measurement.

One embodiment of ablation apparatus 10 is illustrated in Figure 5(a). Expandable member 12 is made of a material that can be an insulator. For purposes of this disclosure, an insulator is a barrier to thermal or electrical energy flow. In this embodiment, expandable member 12 is substantially surrounded by a conforming member 20 which is also called a fluid conduit. Conforming member 20 receives electrolytic solution from expandable member 12, heated or not heated, through a plurality of apertures 22 formed in expandable member 12, and passes it to conforming member 20. Expandable member 12 is made of a material that

permits controlled delivery of the electrolytic solution through one or more distribution ports 21, and can be made of a microporous material that does not include distinct apertures.

In one embodiment, ablation apparatus 10 conforms tightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 24 of conforming member 20. Conforming member 20 is fitted into the entire uterus and expandable member 12 does not have to be moved about the uterus to complete the treatment. Alternatively, ablation apparatus 10 may not entirely fill the uterus, and ablation apparatus 10 is then moved about the uterus in order to ablate all of the endometrium, or those sections where ablation is desired. Selected portions of the endometrium may not be ablated, such as those portions close to the fallopian tubes.

Conforming member 20 is made of a material that substantially conforms to the surface of the endometrium. This provides better conformity than the mere use of expandable member 12, and the delivery of treatment energy to the endometrium is enhanced.

While expandable member 12, with a single interior section 26, is preferred, it will be appreciated that expandable member 12 can be made of different compositions or materials, with one or more open or closed cells or chambers. The plurality of such cells or chambers can be compressed or configured in a small diameter for insertion, and are then expanded after insertion to establish the desired electrical contact with the targeted surface of the endometrium.

Conforming member 20 is made of a material that suitably conforms to a surface to be ablated, and can have a thickness in the range of about 0.01 to 2.0 cm. Conforming member 20 can be made of a foam type material. Suitable materials include but are not limited to, knitted polyester, continuous filament polyester, polyester-cellulose, rayon, polyamide, polyurethane, polyethylene, and the like. Suitable commercial foams

include, (i) Opcell, available from Sentinel Products Corp., Hyannis, Massachusetts and (ii) UltraSorb, HT 4201 or HT 4644MD from Wilshire Contamination Control, Carlsbad, California. Conforming member 20 has characteristics that make it particularly moldable and conformable to irregular surfaces. In one embodiment, conforming member 20 is made of a an open cell foam, or alternatively it can be a thermoplastic film such as polyurethane, low density polyethylene, or may be a silicone rubber. Additionally, conforming member 20 can be capable of extruding conductive materials from conforming member 20 itself. Conforming member 20 can be implanted with conductive ions, and conductive surface 24 can be coated with a material that improves its conductivity.

In an alternate embodiment illustrated in Figure 5(b), expandable member 12 is made of a material that is an insulator to RF energy. In this embodiment, expandable member 12 is substantially surrounded by a first fluid conduit 25, which in turn is surrounded by a second fluid conduit 27, the first and second fluid conduits serving as a conforming member. First fluid conduit receives electrolytic solution from expandable member 12, through a plurality of apertures 29 formed in expandable member 12, and passes it to first fluid conduit. Expandable member 12 is made of a material that permits controlled delivery of the electrolytic solution, and can be made of a microporous material that does not include distinct apertures.

First fluid conduit 25 can be a membrane, such as a microporous membrane, made of Mylar, expanded PFT such as Gortex available from Gore Company, and the like. As a membrane, first fluid conduit 25 is relatively strong, and sufficiently heat resistant for the amount of thermal energy that is supplied to the endometrium. As a membrane, first fluid conduit 25 applies pressure, relative to the electrolytic solution, and thus assists in controlling its flow rate. First fluid conduit 25 can also be made of a foam.

First fluid conduit 25 can be a heat sealed plenum, to distribute

electrolytic solution, if second fluid conduit 27 is made of a foam type of material. It is not needed if second fluid conduit is a perforated film. In this embodiment, ablation apparatus 10 conforms tightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 31 of second fluid conduit. In this case second fluid conduit 27 is fitted into the entire uterus and expandable member 12 does not have to be moved about the uterus to complete the treatment. Alternatively, ablation apparatus 10 may not entirely fill the uterus and ablation apparatus 10 is then moved about the uterus in order to ablate all of the endometrium, or those sections where ablation is desired.

The second fluid conduit 27 acts as a conforming member by substantially conforming to the surface of the endometrium. This provides better conformity than the mere use of expandable member 12, and the delivery of treatment energy to the endometrium is enhanced.

Interior section 33 contains an electrolytic solution, such as saline. The amount of electrolytic fluid in interior section 33 is one of the factors for establishing the flow rate of electrolytic solution out of interior section 33. Expandable member 12 can become more pressurized by increasing the amount of electrolytic solution. As electrolytic fluid enters expandable member 12, the pressure within interior section 33 increases. This increases the flow rate of electrolytic solution out of apertures 29. A reduction in pressure will correspondingly reduce the flow rate. The combination of second fluid conduit 27 and the application of the electrolytic solution through second fluid conduit 27 provides for effective delivery of RF energy to endometrium surface.

Positioned between the first and second fluid conduits 25 and 27 is a plurality of electrodes that collectively can be in the form of a flexible circuit, both denoted as 37, described in greater detail further in this specification. An insulator 39, such as nylon, polyamide, latex, Teflon and the like, is partially deposited on electrodes 37 so that a back side of

second fluid conduit 27 is insulated from the direct delivery of RF energy from that adjacent electrode. Insulator 39 prevents RF energy from electrodes 37 to pass directly from electrodes 37 through second fluid conduit 27. Instead, RF energy is applied indirectly to the endometrium, causing a thermal affect in the tissue. RF energy from electrodes 37 arcs out through first fluid conduit 25 and then through second fluid conduit 27. Expandable member 12 serves as a second insulator.

Figure 5(c) illustrates the case where a plurality of electrodes 41 are positioned on an exterior surface of expandable member 12. There is direct energy delivery to the tissue. This results in an uneven penetration of energy to the endometrium. There is too much ablation for those areas of the endometrium adjacent to an electrode 41. The problem is compounded as the number of electrodes 41 adjacent to the endometrium is increased. As previously mentioned, it has been discovered that insulator 39 provides an even penetration of ablative energy.

As illustrated in Figure 5(d), second fluid conduit 27 can be a heat sealed plenum to distribute electrolytic solution if conforming member is made of a foam type of material. It is not needed if conforming member is a perforated film. In this embodiment, ablation apparatus 10 conforms tightly with the interior of the uterus so that all, or almost all, of the endometrium is in contact with a conductive surface 31 of second fluid conduit 25. In this case, expandable member 12 does not have to be moved about the uterus to complete the treatment. Alternatively, ablation apparatus 10 may not entirely fill the uterus and ablation apparatus 10 is then moved about the uterus in order to ablate all of the endometrium, or those sections where ablation is desired.

While a balloon, with a single interior section 33, is the preferred expandable member, it will be appreciated that the expandable member can be made of different compositions or materials, with one or more open or closed cells or chambers. The plurality of such cells or chambers can

be compressed or configured in a small diameter for insertion and are then expanded after insertion to establish the desired electrical contact with the desired surface of the endometrium.

Interior section 33 contains a electrolytic solution, such as saline. The amount of electrolytic fluid in interior section 33 is one of the factors for establishing the flow rate of electrolytic solution out of interior section 33. Expandable member 12 can become more pressurized by increasing the amount of electrolytic solution. As electrolytic fluid enters expandable member 12, the pressure within interior section 33 increases. This increases the flow rate of eiectrolytic solution out of apertures 29. A reduction in pressure will correspondingly reduce the flow rate.

First fluid conduit 25 is made of a material that suitably conforms to a surface 35 that is to be ablated and can have a thickness in the range of about 0.01 to 2.0 cm. First fluid conduit 25 can be made of a foam type material. Suitable materials include but are not limited to silicon reinforced natural gum rubber, neoprene, soft gum rubber, polyurethane, and the like. First fluid conduit 25 has characteristics that make it particularly moldable and conformable to irregular surfaces. In one embodiment, first fluid conduit 25 is made of a an open cell foam, or alternatively it can be a thermoplastic film such as polyurethane, low density polyethylene, or may be a silicone rubber. Additionally, first fluid conduit 25 can be capable of extruding conductive materials from first fluid conduit 25 itself. First fluid conduit 25 can be implanted with conductive ions, and conductive surface 31 can be coated with a material that improves its conductivity. The combination of first fluid conduit 25 and the application of the electrolytic solution through first fluid conduit 25 provides for the effective delivery of RF energy to endometrium surface 35.

Figure 5(e) illustrates another embodiment of the invention with expandable member 12 having a first side 43, and a second side 45, the second side including a plurality of apertures 29. In this embodiment, the

ablative apparatus 10 is moved about the interior of the uterus 36 where the first side 43 of the device presses against the interior surface 35 of the uterus.

Figures 6(a) - 6(c) illustrate that conforming member 20 can be created by sealing two conforming members 20(a) and 20(b) together. In Figure 6(a), conforming members 20(a) and 20(b) are sealed together between individual electrodes 28. This creates a pocket or zone 30. Zone 30 has a lower porosity for the flow of electrolytic solution than non-zone sections 32, e.g., all other sections of conforming member 20 which do not include a zone 30 with an associated electrode 28. The porosity of non-zone sections 32 is greater than the porosity of zones 30.

Electrolytic solution is released from interior 26 of expandable member 12 and passes through conforming member 20. The differences in porosity is achieved in an open cell foam, with zones 30 having less open cells than non-zone sections 32. Electrolytic solution is retained in zones 30 longer than in non-zone sections 32 and its temperature is elevated. The semi-trapped electrolytic solution in zones 30 combines with electrode 28 to create a larger electrode. The larger electrode produces RF and thermal energy to conforming member 20, which is transferred to tissue through conductive surface 24.

Electrolytic solution travels through zones 30 at a slow enough rate to create this larger electrode effect. The porosity of zones 30 is selected so that electrolytic solution remains in the respective zone 30 sufficiently long enough to become heated to an elevated temperature and produce the larger electrode effect.

In Figure 6(a), conforming members 20(a) and 20(b) are sealed in non-zone areas 32 and along the peripheries of 20(a) and 20(b). This creates a structure that, (i) conforms closely to the endometrium or other organ/lumen structures, (ii) effectively introduces electrolytic solution to the desired tissue site and (iii) with the inclusion of zones 30 with lower

porosity, electrolytic solution is elevated to a higher temperature. The result is a greater RF and thermal effect that is evenly applied to the tissue site such as the endometrium.

Figure 6(b) illustrates conforming members 20(a) and 20(b) sealed at electrode 28 to create zone 30, and not sealed at non-zone sections 32 except at the peripheries of conforming members 20(a) and 20(b).

Figure 6(c) illustrates zone 30 filled with electrolytic solution which becomes heated to a desired elevated temperature while it remains in zone 30.

As an example of ablation apparatus 12, a foam patch with zones 30 and non-zone sections 32, utilized two pieces of UltraSorb foam which were sealed between 0.004 inch by 0.016 inch (SST) flat electrode wire with approximately 80 Ω/foot. About 1.0 inch of SST wire was exposed in the foam. Different foam thickness were used and included, (i) 1/16 inch by 1/8 inch, (ii) 1/8 inch by 1/16 inch and (iii) 1/16 inch by 1/16 inch. The foam size was about 1.0 inch by 1.0 inch. A return electrode, through a sheet of brass, was utilized. A 0.9% saline solution was utilized and placed in a test bath. The presoaked foam patch was laid inside the test bath. The system was energized and temperature across the path was monitored. Temperature T_2 represented the temperature in the zone, while temperatures T_1 and T_3 represented temperatures in adjacent non-zone sections 32.

The results are shown in Figures 7 and 8. Temperatures in zone 30 were higher than temperatures in adjacent non-zone sections 32. In Figure 7, 50 Ω was connected, and the impedance was about 85 Ω. In Figure 8, 50 Ω was connected, and the impedance was about 90 Ω.

Interior 26 can contain heated electrolytic solution, such as saline. The amount of electrolytic fluid in interior 26 is one of the factors for establishing the flow rate of electrolytic solution out of interior 26. Expandable member 12 can become more pressurized by increasing the

amount of electrolytic solution. As electrolytic fluid enters expandable member 12, the pressure within interior 26 increases. This increases the flow rate of electrolytic solution out of apertures 22. A reduction in pressure will correspondingly reduce the flow rate. Electrolytic solution is introduced into interior 26 through fluid distribution ports 21 formed in, for example, core lumen 15, or it can be introduced through a separate fluid conduit.

Heated electrolytic solution can be delivered from expandable member 12, through conforming member 20, and is then delivered to the tissue to be ablated. Fluid flow can be continuous or non-continuous to the tissue site.

As shown in Figure 9 a flexible circuit 34 is made of individual electrodes 28 in zones 30 and positioned within conforming member 20. Figure 10 shows individual electrodes 28, with thermocouples, that can be used and multiplexed in either of monopolar or bipolar schemes.

Referring again to Figure 9, electrodes 28 and zones 30 are capable of multiplexing so that only certain electrodes 28 deliver RF and thermal energy at a particular time period. Zones 30 provide individual ablative coverage, and delivery, for the entire conductive surface 24. In this regard, the plurality of zones 30 can provide ablative regions individually everywhere on conductive surface 24.

The selectivity can be the even application of RF energy everywhere it is applied to the endometrium so that the same depth of endometrium is ablated, or the amount of applied energy can be variable, depending on the characteristics of the endometrium surface. In this instance, certain sections of the endometrium will have more tissue ablated than other sections.

Each zone 30 connects to a separate feedwire 34, with all of the wires going to a ribbon connector 38. Feedwires 34 are insulated. Each electrode 28 and zone 30 is wired with a constantan wire in order to

receive RF energy from an RF energy source. A copper wire is connected to each constantan wire. This results in the formation of a T type thermocouple "TC".

RF power can be sequentially supplied to each electrode 28, to feedwire 34 in ribbon connector 38, or it can be applied to only certain selected feedwires 34, enabling only selected electrodes 28 along with the electrolytic solution in zones 30 to deliver RF and thermal energy individually to the endometrium. In this way electrodes 28 can be multiplexed. The sizes of individual electrodes 28 are designed to provide the correct current density.

Referring now to Figure 11, segments 51 in a cut-away view is shown with insulator 39 removed in order to show the plurality of segments 51, and their relationship to expandable member 12. Electrodes 28 can also be positioned on support member 49. Printed circuit 28 can be formed by etching, deposition or lithography methods well known to those skilled in the art. Printed circuit 28 is formed of individual segments 51 and is capable of multiplexing so that only certain segments deliver RF energy at a particular time period. Although segments 51 are separated from conductive surface 31 of second fluid conduit 27, they provide individual ablative coverage, and delivery, for the entire conductive surface 31. In this regard, the plurality of segments 51 provide ablative regions individually everywhere on conductive surface 31. Because segments 51 are not directly positioned adjacent to or on the exterior surface of expandable member 12, and with the inclusion of insulator 40 to isolate segments 51 from first fluid conduit 25, there is a selective application of ablative energy to the endometrium.

The selectivity can be even application of RF energy everywhere it is applied to the endometrium so that the same depth of endometrium is ablated everywhere, or the amount of applied energy can be variable, depending on the characteristics of the endometrium surface. In this

instance, certain sections of the endometrium will have more tissue ablated than other sections. The problems of uneven penetration of energy, shown in Figure 5(c), are overcome by sandwiching partially insulated electrodes 28 between first fluid conduit 25 and second fluid conduit, or foam, 27.

As shown in Figure 12, a plurality of filaments 51 can be optionally included in second fluid conduit 27. These help direct RF energy to conductive surface 31.

Referring now to Figure 13, one or more impedance monitors 40 can be used to confirm, before an ablation event, that good coupling of energy is achieved. Also included is one or more temperature monitors/sensors 42. Thermal sensors 42 are conventional thermistors or thermocouples, and are positioned adjacent to or on electrodes 28. Electrodes 28 are capable of monitoring circuit continuity. Impedance is monitored between each electrode 28 and zone 30 and a ground electrode when operated in a monopolar mode, or between electrodes 20 operating in a bipolar mode.

In Figure 14, a cross-sectional view of core lumen 15 shows that a variety of conduits, wires and fibers are housed in the lumen. These include, but are not limited to, viewing and illumination optical fibers 44, well known to those skilled in the art, which can deliver light, such as from a Xenon source, to viewing optics 46 (Figures 1(a), 1(b) and 1(c)) a tension wire 48 that connects to hinge 18; an RF cable 50 connecting feedwires 34 to an RF source; an electrolytic solution delivery conduit 52 with associated fluid distribution port 21; and an electrical lead 54 which couples an ultrasound energy source 56 to one or more transducers 58.

Viewing optics 46 can be a 70 degree lens, which permits a lateral field of view. Additionally, the combination of optical fibers 44 and viewing optics 46 can be in the form of a flexible viewing scope that is capable of providing a full field of view within the interior of the uterus.

A two-way valve is included with delivery conduit 52. A pump or other similar device advances electrolytic solution to and from expandable

member 12 through delivery conduit 52. When the procedure is completed, electrolytic solution is removed from expandable member 12 through delivery conduit 52. Core lumen 15 is then rotated, in a twisting type of motion, in order to helically wrap the entire ablation apparatus 10, e.g., expandable member 12 and conforming member 20 around core lumen 15. Substantially all of the electrolytic solution is removed. Ablation apparatus 10 is then retracted back into introducer sleeve 14. It is then removed from the uterus. Alternatively, the entire ablation apparatus 10 can be retracted directly into introducer sleeve 14.

Electrolytic solution source 72 can include a pump/pressure flow control device 80, as is well known to those skilled in the art. A heating device 82, for heating the electrolytic solution, is associated with electrolytic solution source 72, or it can be positioned in expandable member 12. Suitable heating devices include but are not limited to coils, bipolar electrodes, catalysts, and other devices, as are well known to those skilled in the art. An ultrasound source 84 is coupled to one or more ultrasound transducers 58 that are positioned in or on conforming member 20. Ultrasound transducers 58 can be positioned apart from conforming member 20. An output is associated with ultrasound source 84 and RF energy source 68.

Each ultrasound transducer 58 can include a piezoelectric crystal mounted on a backing material. An ultrasound lens, fabricated on an electrically insulating material, is mounted between the piezoelectric crystal and conforming member 20. The piezoelectric crystal is connected by electrical leads 54 to ultrasound power source 86. Each ultrasound transducer 58 transmits ultrasound energy through conforming member 20 into adjacent tissue. Ultrasound transducers 58 can be in the form of an imaging probe such as Model 21362, manufactured and sold by Hewlett Packard Company, Palo Alto, California.

Thermal sensors 42 permit accurate determination of the surface temperature of the endometrium at conductive surface 24 adjacent to ultrasound transducers 58. Thermal sensors 42 are in thermal proximity to the piezoelectric crystals.

As previously mentioned, ablation apparatus 10 can be used with a variety of different body organs or lumens including the uterus. Electrodes 28 and zones 30 can be activated to ablate the endometrium. Ablation apparatus 10 can be multiplexed and deliver RF and thermal energy to only certain sections of the endometrium. Each zone 30 can provide 50 watts or less of power.

As previously mentioned, ablation apparatus 10 can be used with a variety of different body organs. In Figure 15, ablation apparatus 10 is positioned and retained in the uterus 36. Electrodes 38 or individual or a plurality of segments 51 can be activated to ablate the endometrium. Ablation apparatus 10 is multiplexed and delivers RF energy to only certain sections of the endometrium so that, for instance, segment 51(a) is first activated, then segment 51(b), segment 51(c) and so on. For example, each segment can provide 51 watts or less of power.

Referring now to Figure 16, a power supply 86 feeds energy into RF power generator (source) 68 and then to ablation apparatus 10. A multiplexer 88 measures current, voltage and temperature, at the numerous temperature sensors, going to each electrode 28 and zone 30 of ablation apparatus 10. Electrodes 28 and zones 30 can be individually measured during an ablation event at that particular sensor. Multiplexer 88 is driven by controller 78, which can be a digital or analog controller, or a computer with software. When controller 78 is a computer, it can include a CPU coupled through a system bus. This system can include a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as known in the art. Also coupled to the bus are a program memory and a data memory.

An operator interface 90 includes operator controls 92 and a display 94. Controller 78 is coupled to the imaging systems, including transducers 58, thermal sensors 42, flexible circuit 34 (current and voltage), and viewing optics 46 and optical fibers 44.

Current and voltage are used to calculate impedance. Temperature and impedance are measured and then treatment can begin. Preferably, only one electrode 28 and zone 30 ablates at a time. Diagnostics are done either optically or through ultrasound. Diagnostics can be performed both before ablation of the endometrium, and also after ablation as a check to ascertain the effectiveness of the treatment.

Thermal sensors 42, and sensors contained within RF energy source 68, measure voltage and current that is delivered to the endometrium. The output for these sensors is used by controller 78 to control the delivery of RF power. Controller 78 can also control temperature and power. An operator set level of power, and/or temperature, may be determined and this will not be exceeded. Controller 78 maintains the set level under changing conditions. The amount of RF and thermal energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 78, as well as a pre-set amount of energy to be delivered can also be profiled.

Feedback can be the measurement of impedance or temperature. It occurs either at controller 78, or at RF energy source 68 if it incorporates a controller. Impedance measurement can be achieved by supplying a small amount of non-therapeutic RF energy. Voltage and current are then measured to confirm electrical contact.

Circuitry, software and feedback to controller 78 result in full process control and are used to change, (i) power (modulate) - including RF, incoherent light, microwave, ultrasound and the like, (ii) the duty cycle (on-off and wattage), (iii) monopolar or bipolar energy delivery, (iv) fluid (electrolyte/saline) delivery, temperature of the fluid, flow rate and pressure

and (v) determine when ablation is completed through time, temperature and/or impedance. These process variables can be controlled and varied based on tissue temperature monitored at multiple sites on the ablating surface, and impedance to current flow monitored at each electrode 28 and zone 30, indicating changes in current carrying capability of the tissue during the ablative process. Additionally, controller 78 can provide multiplexing, monitor circuit continuity, and/or determine which electrode 28 and zone 30 is activated.

A block diagram of one embodiment of suitable processing circuitry is shown in Figure 17. Thermal sensors 42 and transducers 58 are connected to the input of an analog amplifier 96. Thermal sensors 42 can be thermistors which have a resistance that varies with temperature. Analog amplifier 96 can be a conventional differential amplifier circuit for use with thermistors and transducers. The output of analog amplifier is sequentially connected by an analog multiplexer 98 to the input of an analog to digital converter 100. The output of amplifier 96 is a voltage which represents the respective sensed temperatures. The digitized amplifier output voltages are supplied by analog to digital converter 100 to a microprocessor 102. Microprocessor 102 calculates the temperature or impedance of the tissue. Microprocessor 102 can be a type 68000. However, it will be appreciated that any suitable microprocessor, or general purpose digital or analog computer, can be used to calculate impedance or temperature.

Microprocessor 102 sequentially receives and stores digital representations of impedance and temperature at electrodes 28 and zones 30. Each digital value received by microprocessor 102 corresponds to different temperatures and impedances.

Calculated temperature and impedance values can be indicated on display 94. Alternatively, or in additional to the numerical indication of temperature or impedance, calculated impedance and temperature values

can be compared by microprocessor 102 with temperature and impedance limits. When the values exceed predetermined temperature or impedance values, a warning can be given on display 94, and additionally, the delivery of RF energy to that electrode 28 and zone 30 is then multiplexed to another electrode 28 and zone 30. A control signal from microprocessor 102 can reduce the power level supplied by RF power source 68, or deenergize the power delivered to a particular electrode 28 and zone 30.

Thus, controller 78 receives and stores the digital values which represent temperatures and impedances sensed. Calculated surface temperatures and impedances can be forwarded by controller 78 to display 94. If desired, the calculated surface temperature of the endometrium is compared with a temperature limit, and a warning signal can be sent to display 94. Similarly, a control signal can be sent to RF energy source 68 when temperature or impedance values exceed a predetermined level.

The foregoing description of preferred embodiments of the present invention has been provided for the purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. The embodiments were chosen and described in order to best explain the principles of the invention and its practical application, thereby enabling others skilled in the art to understand the invention for various embodiments and with various modifications as are suited to the particular use contemplated. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. An apparatus for ablating an inner layer of an organ or body lumen, comprising:

an expandable member having an interior section for housing an electrolytic solution;

a conforming member made of a material capable of substantially conforming to a portion of the inner layer of the organ, the conforming member delivering the electrolytic solution housed within the expandable member to the inner layer of the organ;

one or more electrodes positioned in or on the conforming member for delivering RF energy to the inner layer of the organ;

an electrical connector device connecting the one or more electrodes to an RF energy source; and

an electrolytic solution delivery tube for delivering the electrolytic solution from the electrolytic solution source to the expandable member.

2. The ablation apparatus according to claim 1, wherein the expandable member includes a plurality of apertures through which the electrolytic solution flows from the expandable member.

3. The ablation apparatus according to claim 2, wherein the expandable member is formed of a nonporous material

4. The ablation apparatus according to claim 3, wherein the expandable member is positioned within the conforming member.

5. The ablation apparatus according to claim 1, further comprising:

a membrane positioned between the expandable member and the conforming member, the membrane adapted to receive the electrolytic solution from the expandable member and deliver the electrolytic solution to the conforming member.

6. The ablation apparatus according to claim 1, wherein the one or more electrodes form a printed circuit that is multiplexed.

7. The ablation apparatus according to claim 6, wherein the printed circuit includes a plurality of segments.

8. The ablation apparatus according to claim 1, wherein the organ is the uterus and the inner layer is the endometrium.

9. An apparatus for ablating an inner layer of an organ or body lumen, comprising:

an expandable member having an interior section for housing an electrolytic solution;

a conforming member made of a material capable of substantially conforming to a portion of the inner layer of the organ, the conforming member delivering the electrolytic solution housed within the expandable member to the inner layer of the organ;

one or more electrodes positioned in or on the conforming member for delivering RF energy to the inner layer of the organ;

an electrical connector device connecting the one or more electrodes to an RF energy source;

an electrolytic solution delivery tube for delivering electrolytic solution from the electrolytic solution source to the expandable member;

and

a feedback device which monitors a characteristic of the inner layer and, in response, controls the delivery of RF energy to the one or more electrodes.

10. The ablation apparatus according to claim 9, wherein the feedback device monitors an impedance of the inner layer at a portion of the inner layer.

11. The ablation apparatus according to claim 9, wherein the feedback device monitors a temperature of the inner layer at a portion of the inner layer.

12. The ablation apparatus according to claim 9, wherein the feedback device includes a controller.

13. The ablation apparatus according to claim 12, wherein the feedback device includes a multiplexer.

14. The ablation apparatus according to claim 9, wherein the one or more electrodes are multiplexed.

15. The ablation apparatus according to claim 9, wherein the one or more electrodes form a printed circuit.

16. The ablation apparatus according to claim 15, wherein the printed circuit includes one or more impedance monitors.

17. The ablation apparatus according to claim 16, wherein the printed circuit includes one or more temperature monitors.

18. The ablation apparatus according to claim 15, wherein the feedback device monitors continuity of the circuit.

19. An apparatus for ablating an inner layer of an organ or body lumen, comprising:

an expandable member having an interior section for housing an electrolytic solution;

a conforming member made of a material capable of substantially conforming to a portion of the inner layer of the organ, the conforming member delivering the electrolytic solution housed within the expandable member to the inner layer of the organ;

a plurality of electrodes positioned in or on the conforming member for delivering RF energy to the inner layer of the organ, each electrode including an insulator formed on a surface of the electrode;

an electrical connector device connecting the one or more electrodes to an RF energy source; and

an electrolytic solution delivery tube for delivering the electrolytic solution from the electrolytic solution source to the expandable member.

20. The ablation apparatus according to claim 19, wherein the plurality of RF electrodes are positioned on a support member.

21. The ablation apparatus according to claim 19, wherein the plurality of electrodes form a flexible circuit.

22. The ablation apparatus according to claim 21, wherein the flexible circuit is a printed circuit.

23. The ablation apparatus according to claim 19, wherein the expandable member is expanded mechanically.

24. The ablation apparatus according to claim 19, wherein the expandable member is formed of a nonporous material.

25. The ablation apparatus according to claim 19, wherein the conforming member is made of a foam.

26. The ablation apparatus according to claim 19, wherein the expandable member is formed of an insulating material.

27. The ablation apparatus according to claim 26, wherein the plurality of electrodes form a flexible circuit.

28. The ablation apparatus according to claim 27, wherein the flexible circuit is a printed circuit.

29. The ablation apparatus according to claim 26, wherein the expandable member is expanded mechanically.

30. The ablation apparatus according to claim 26, wherein the expandable member is formed of a nonporous material.

31. The ablation apparatus according to claim 26 wherein the conforming member is made of a foam.

32. An apparatus for ablating an inner layer of an organ or body lumen, comprising:

an expandable member having an interior section for housing an electrolytic solution;

a conforming member made of a material capable of substantially conforming to a portion of the inner layer of the organ, the conforming

member delivering the electrolytic solution housed within the expandable member to the inner layer of the organ, the conforming member including non-zone areas with a first porosity rate for delivering electrolytic solution to the inner layer and zone areas for housing an electrode and electrolytic solution, the zone areas having a second porosity rate that is less than the first porosity rate such that the electrolytic solution passes through the zone areas at a slower rate than through the non-zone areas;

one or more electrodes positioned in or on the conforming member for delivering RF energy to the inner layer of the organ;

an electrical connector device connecting the one or more electrodes to an RF energy source; and

an electrolytic solution delivery tube for delivering the electrolytic solution from the electrolytic solution source to the expandable member.

33. The ablation apparatus according to claim 32, wherein the conforming member is made of an open cell material.

34. The ablation apparatus according to claim 32, wherein the conforming member is made of an open cell material, and the zone areas have less open cells than the non-zone areas.

35. The ablation apparatus according to claim 34, wherein the conforming member is made of an open cell foam.

36. The ablation apparatus according to claim 32, wherein the conforming member is formed of two pieces of open cell foam material sealed together in the non-zone areas.

37. The ablation apparatus according to claim 32, wherein the conforming member is two pieces of open cell foam material that are sealed together in the zone.

38. The ablation apparatus according to claim 32, wherein the ablation apparatus includes a plurality of electrodes.

39. The ablation apparatus according to claim 32, wherein each electrode of the plurality of electrodes is associated with a particular zone.

40. The ablation apparatus according to claim 32, further comprising:

a groundpad electrode attached to an exterior surface of a patient.

41. The ablation apparatus according to claim 32, further comprising:

an electrolytic solution source; and

a fluid delivery device for delivering electrolytic solution from the electrolytic solution source to the interior of the expandable member.

42. The ablation apparatus according to claim 32, further comprising:

a heating device positioned within the expandable member.

43. The ablation apparatus according to claim 32, wherein the expandable member is expandable mechanically.

44. The ablation apparatus according to claim 32, wherein the expandable member is expandable by a fluidic medium.

45. The ablation apparatus according to claim 44, wherein the fluid medium is the electrolytic solution.

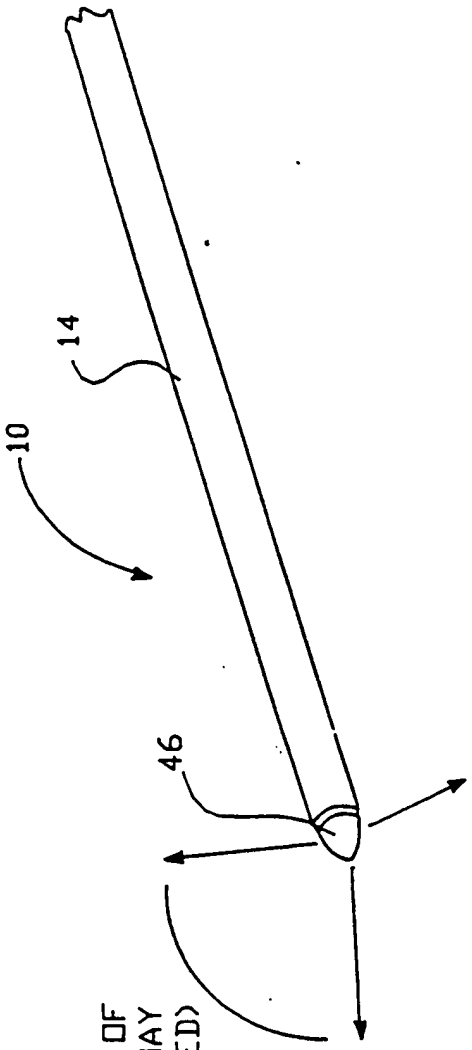

14
10
46
FIELD OF VIEW (MAY BE ROTATED)

FIG. 1(A)

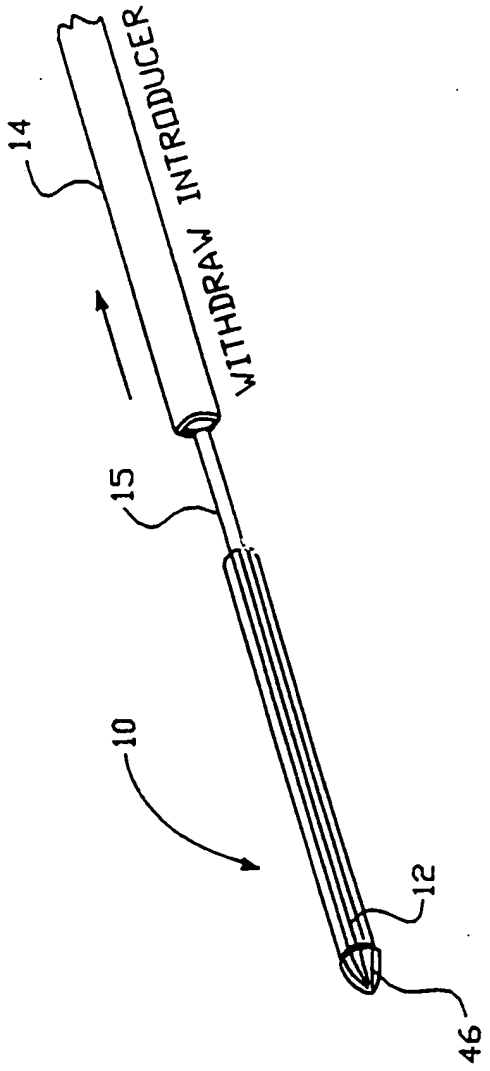

14
WITHDRAW INTRODUCER
15
10
12
46

FIG. 1(B)

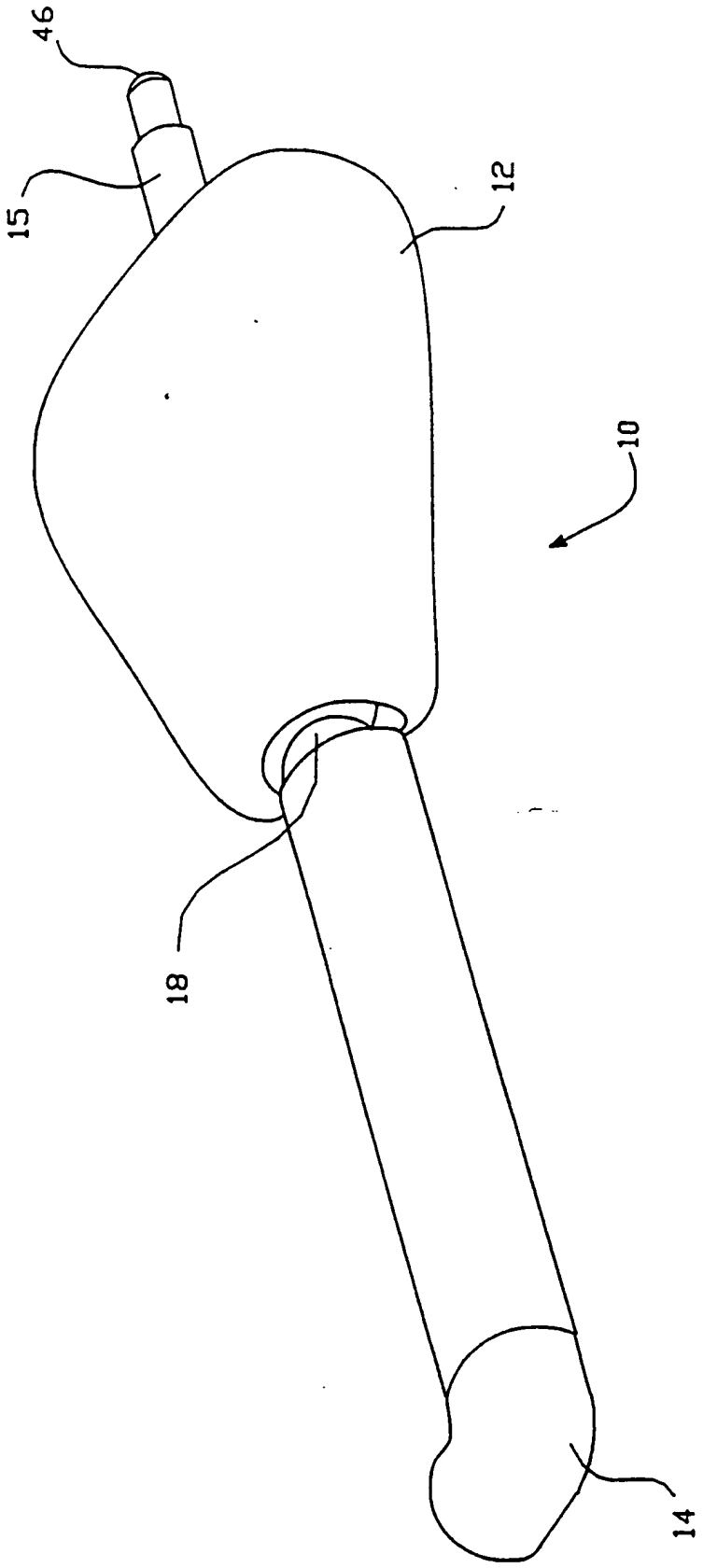


FIG. 1(C)

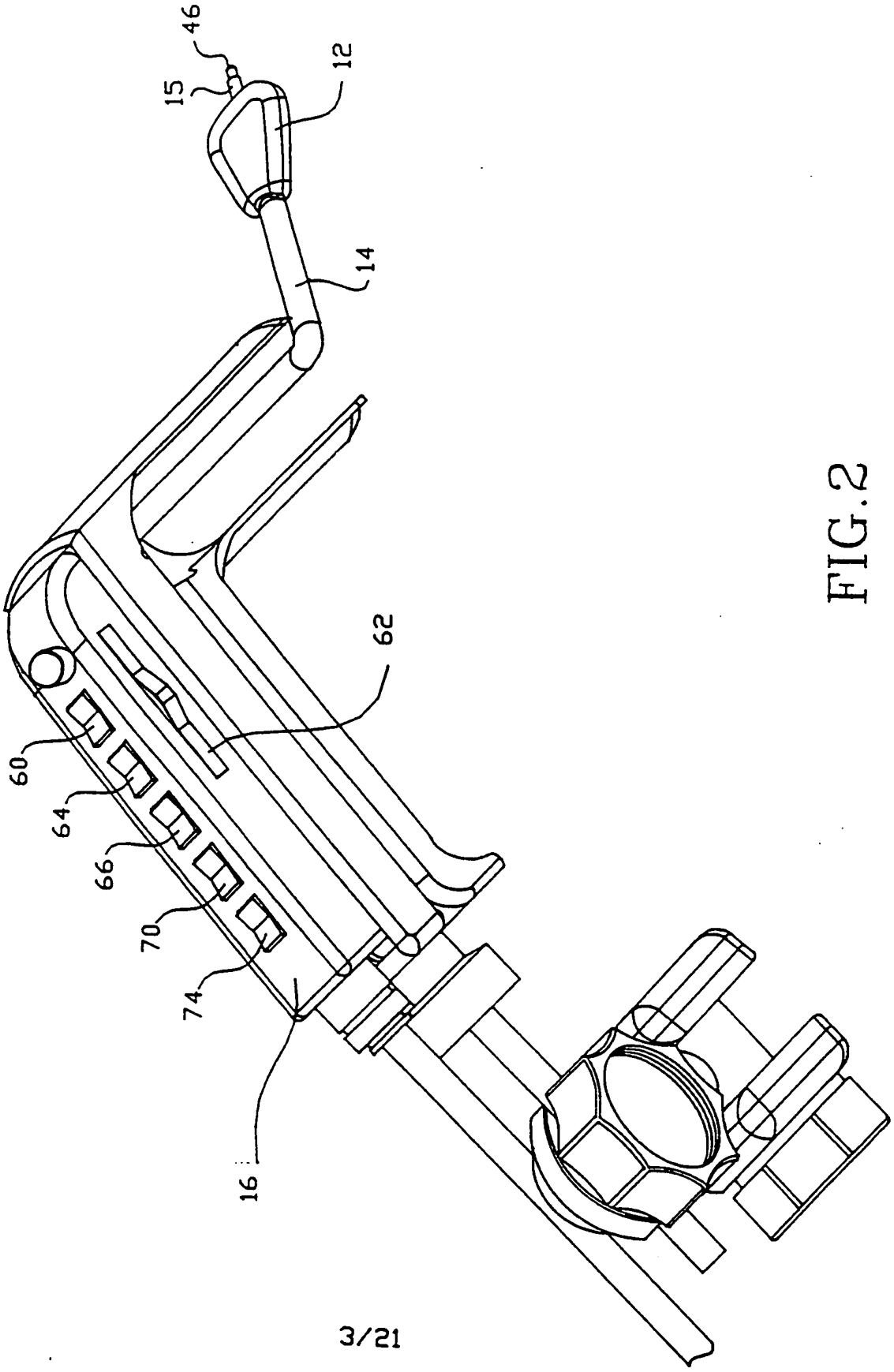


FIG.2

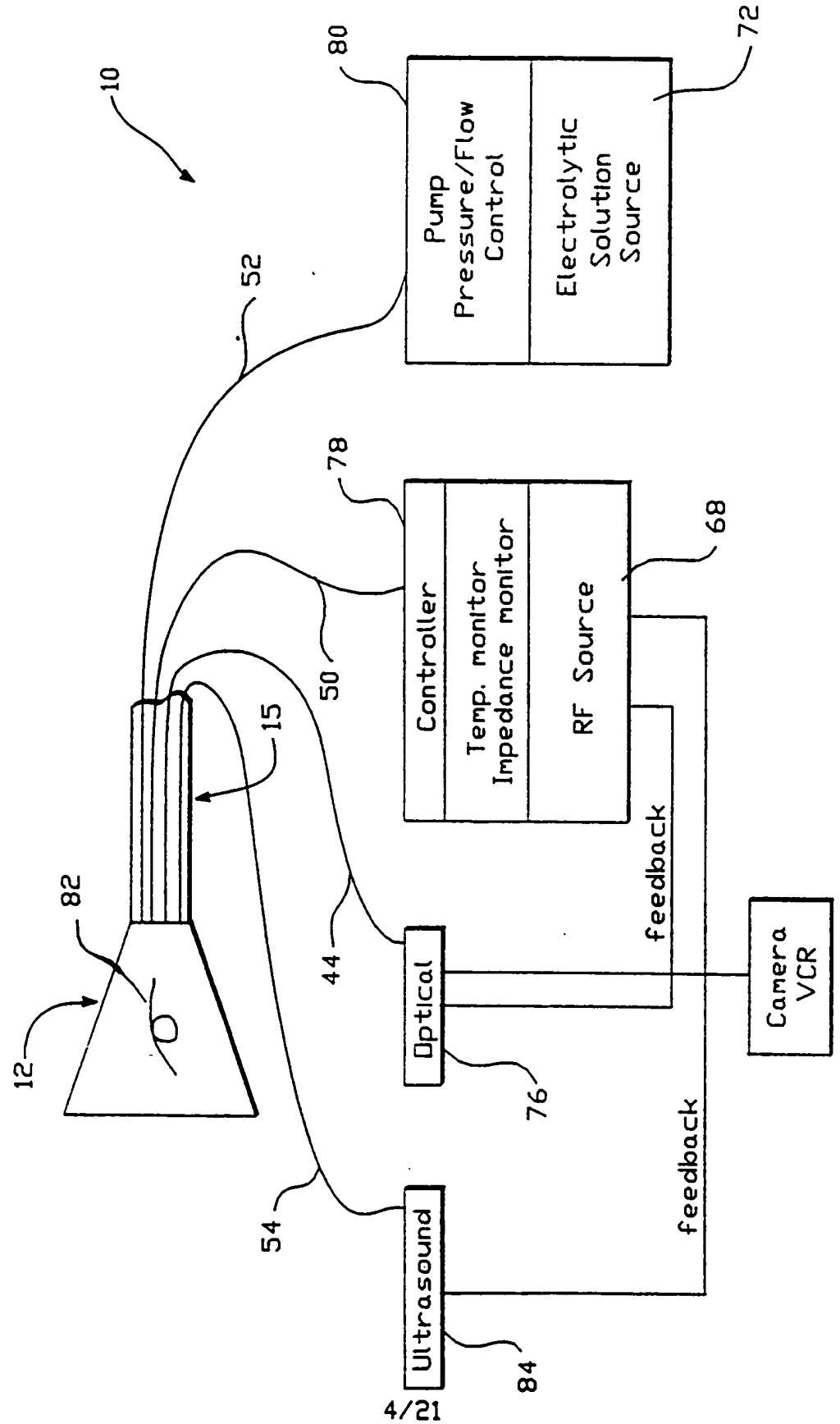

10
80
72
Pump
Pressure/Flow
Control
Electrolytic
Solution
Source
52
78
Controller
Temp. monitor
Impedance monitor
RF Source
68
50
15
82
12
44
Optical
feedback
Camera
VCR
76
54
Ultrasound
feedback
84

FIG.3

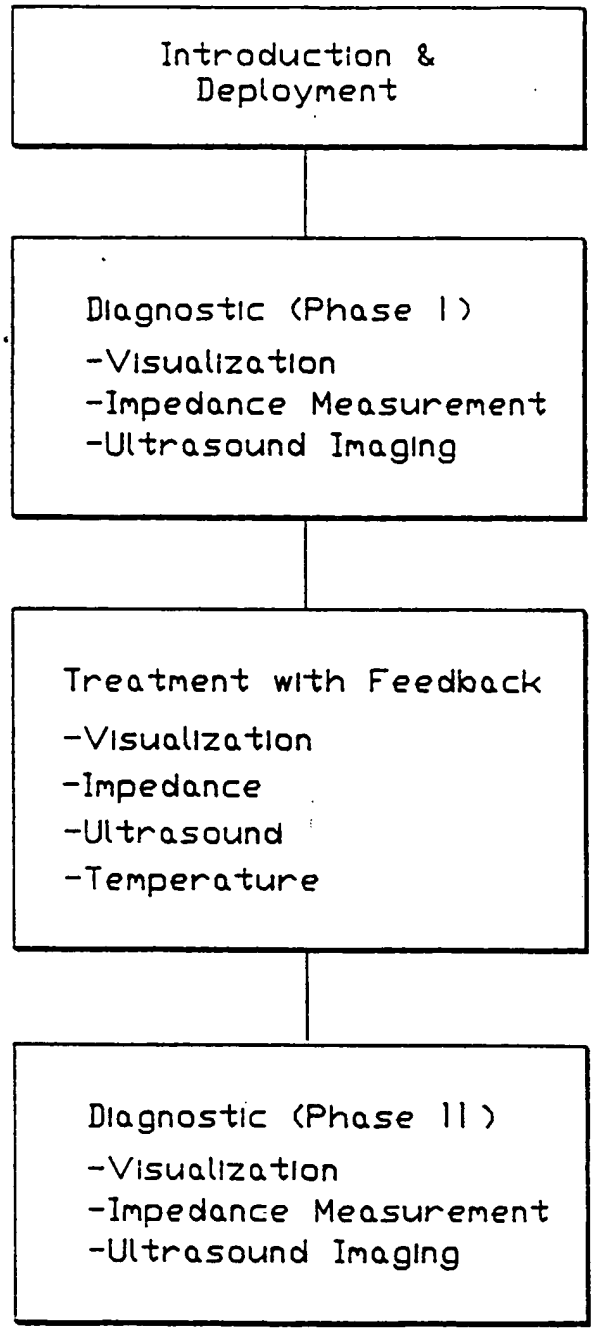

Introduction & Deployment
Diagnostic (Phase I)
-Visualization
-Impedance Measurement
-Ultrasound Imaging
Treatment with Feedback
-Visualization
-Impedance
-Ultrasound
-Temperature
Diagnostic (Phase II)
-Visualization
-Impedance Measurement
-Ultrasound Imaging

FIG.4

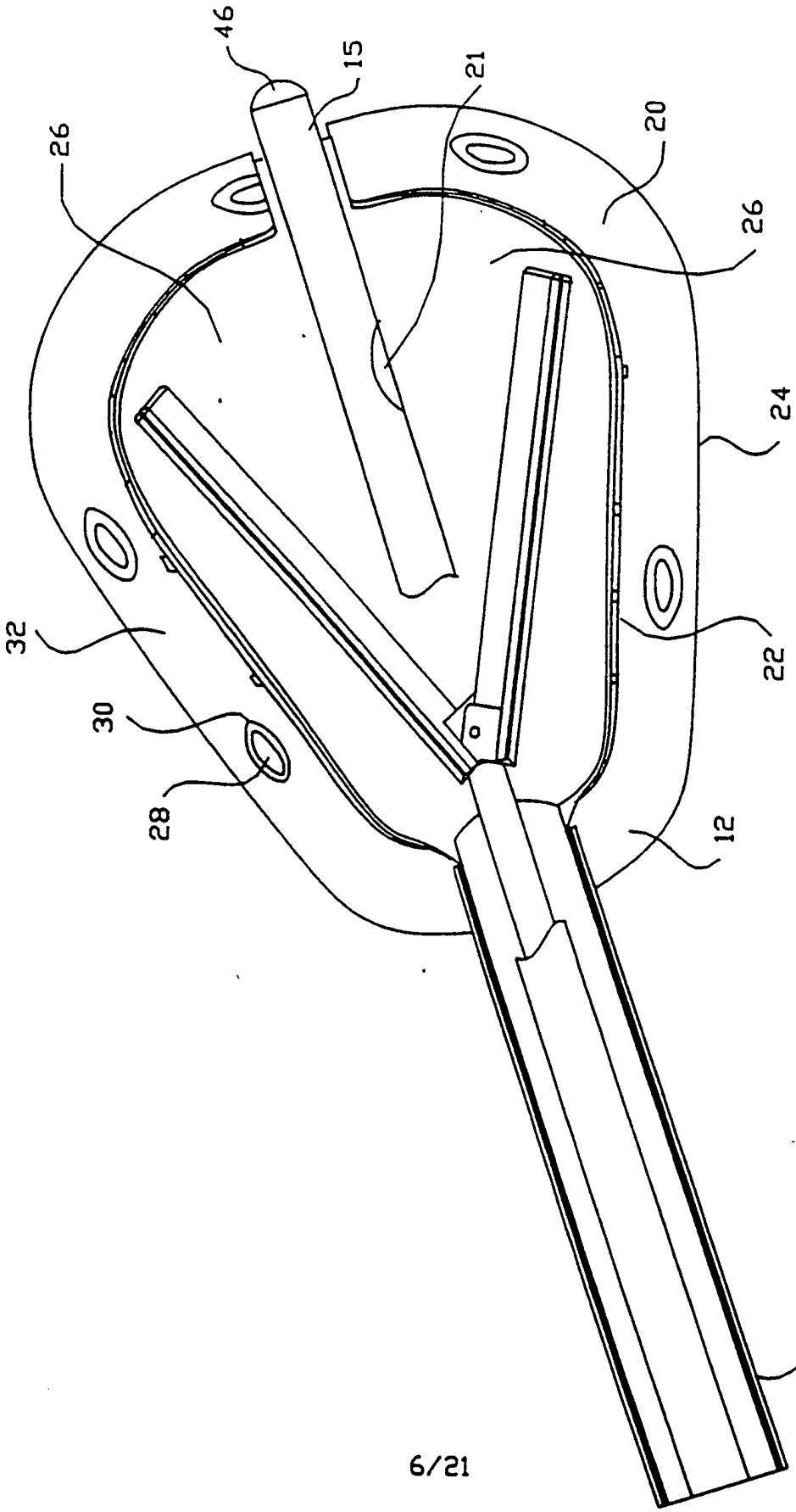


FIG.5(A)

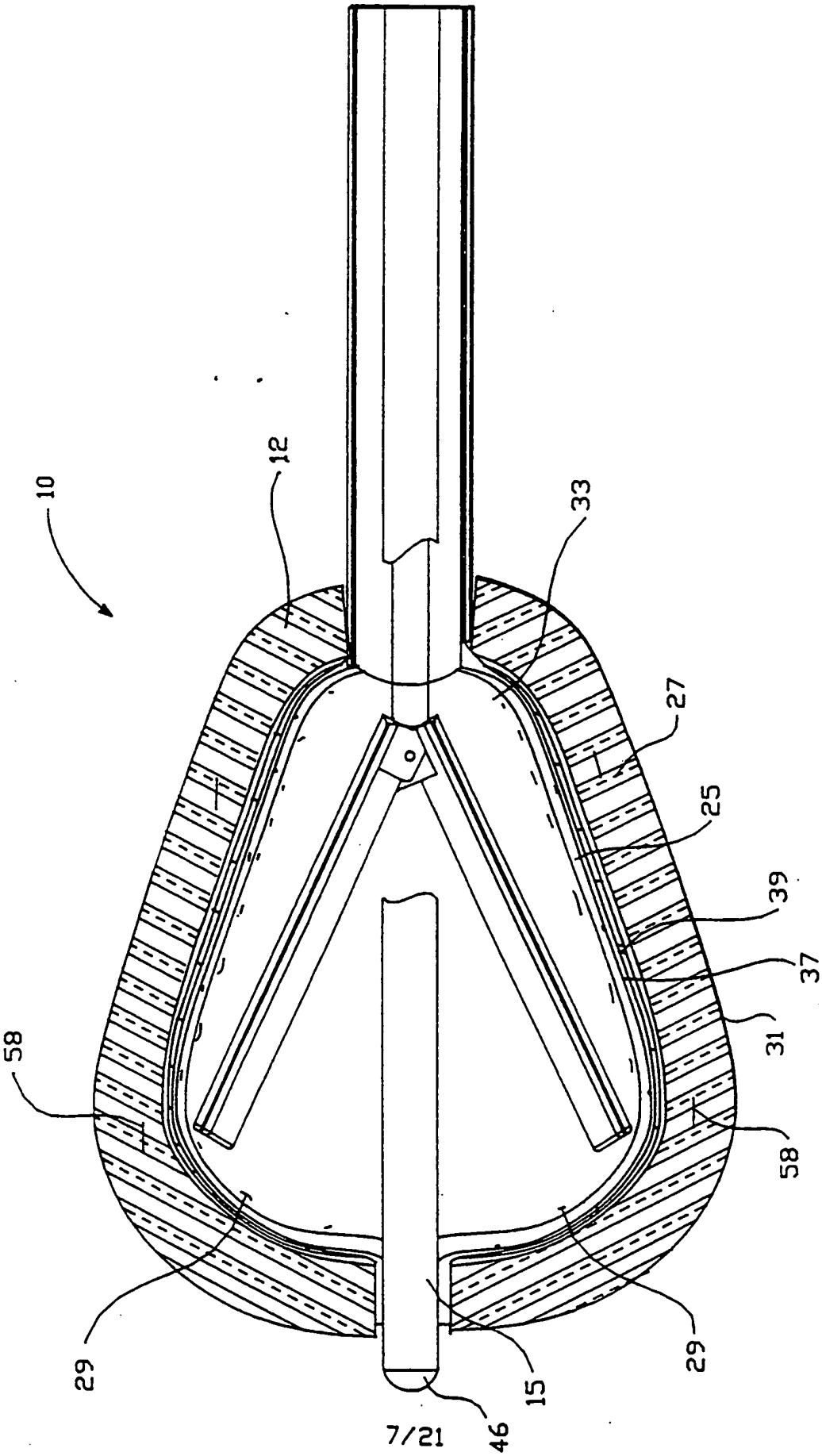


FIG.5(B)

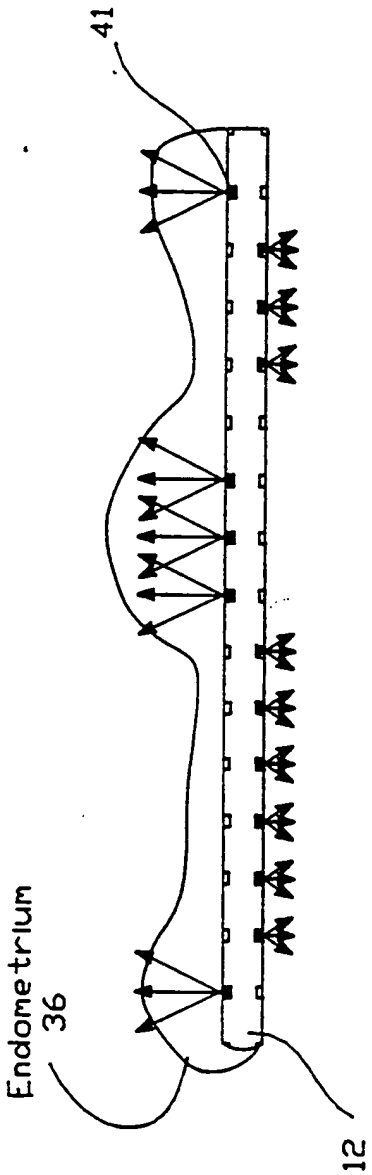


FIG.5(C)

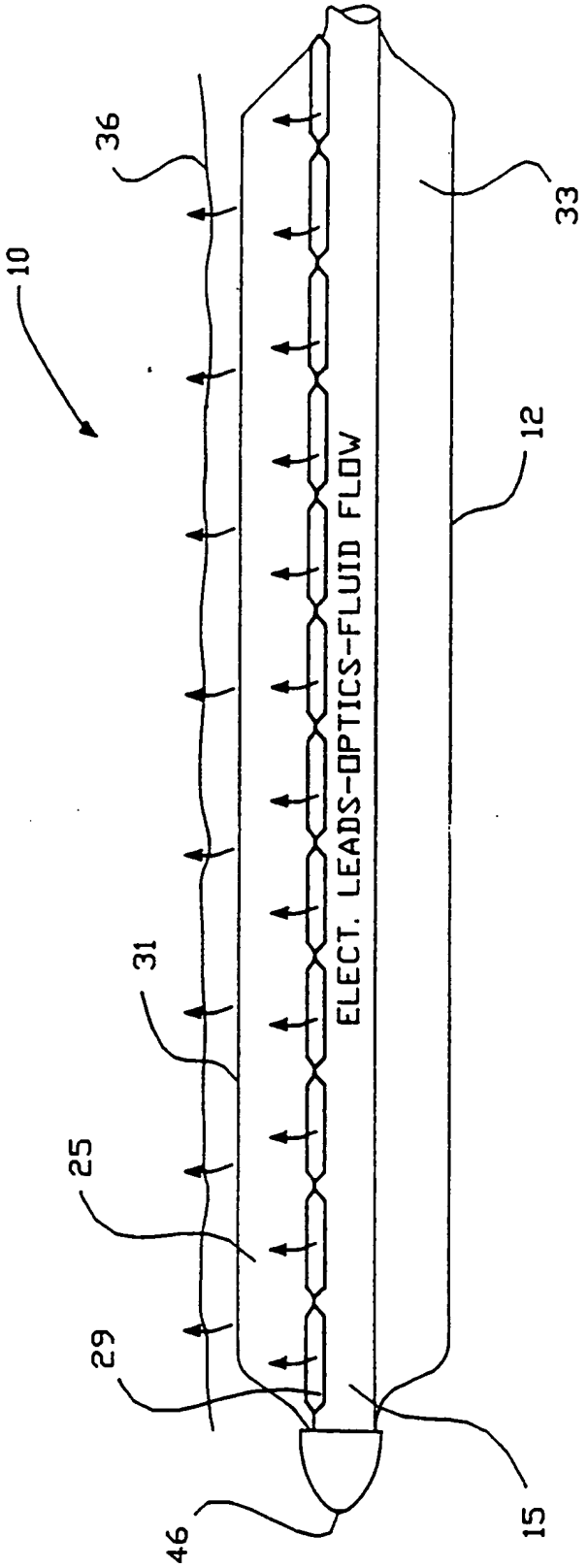


FIG.5(D)

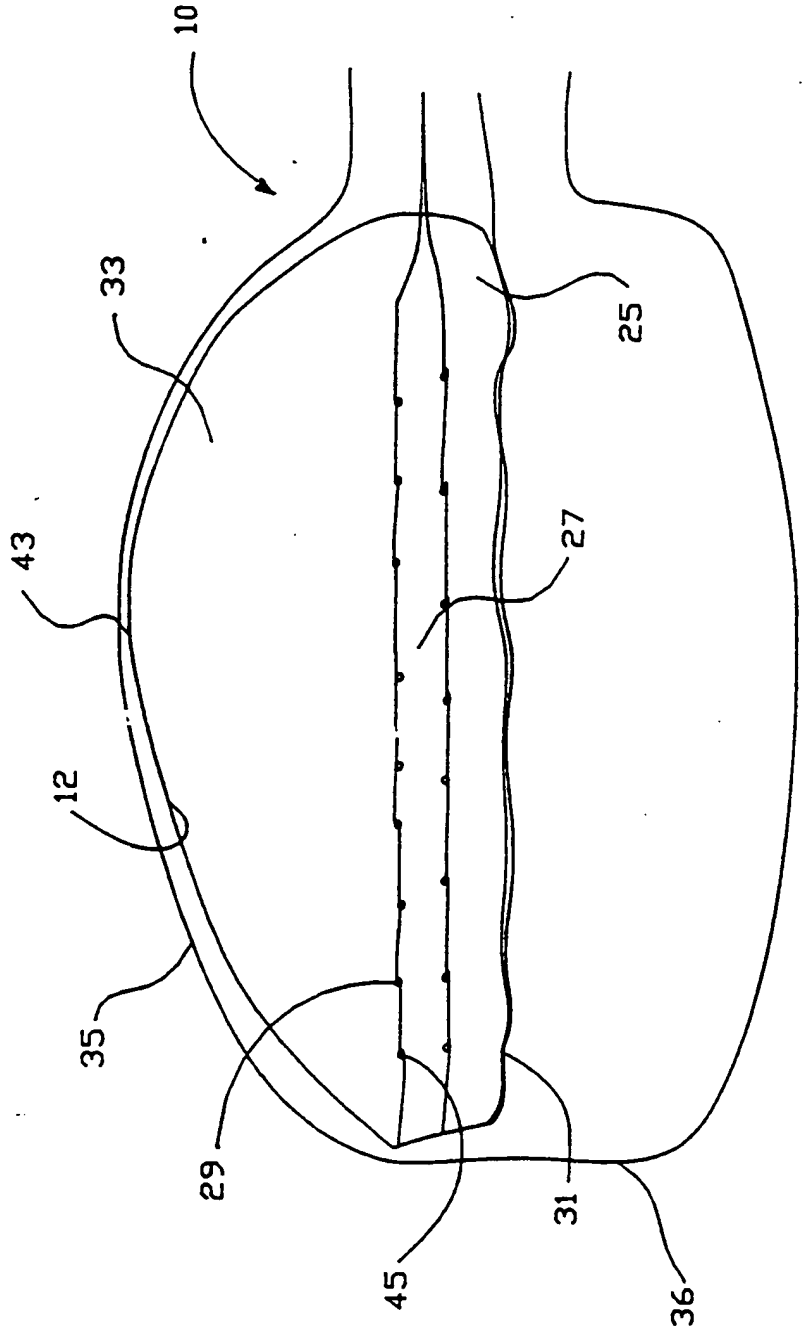


FIG.5(E)

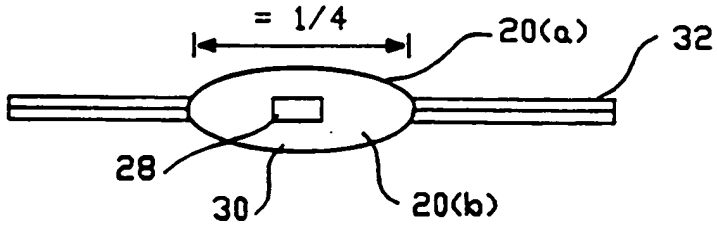


FIG.6(A)

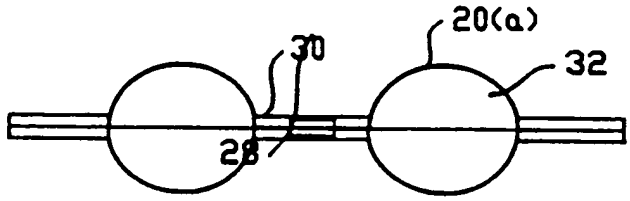


FIG.6(B)

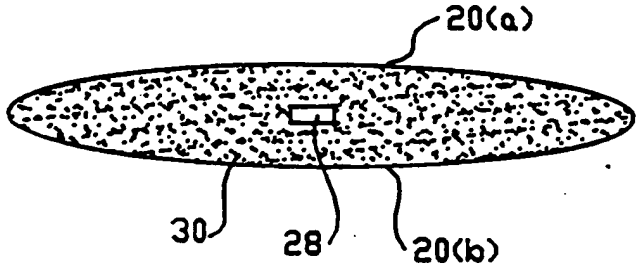
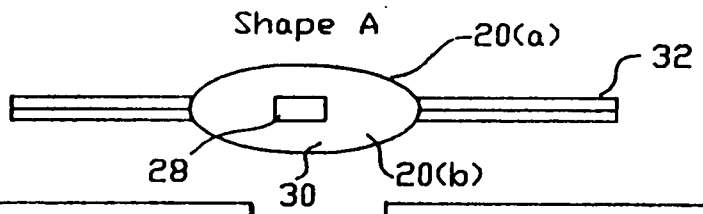
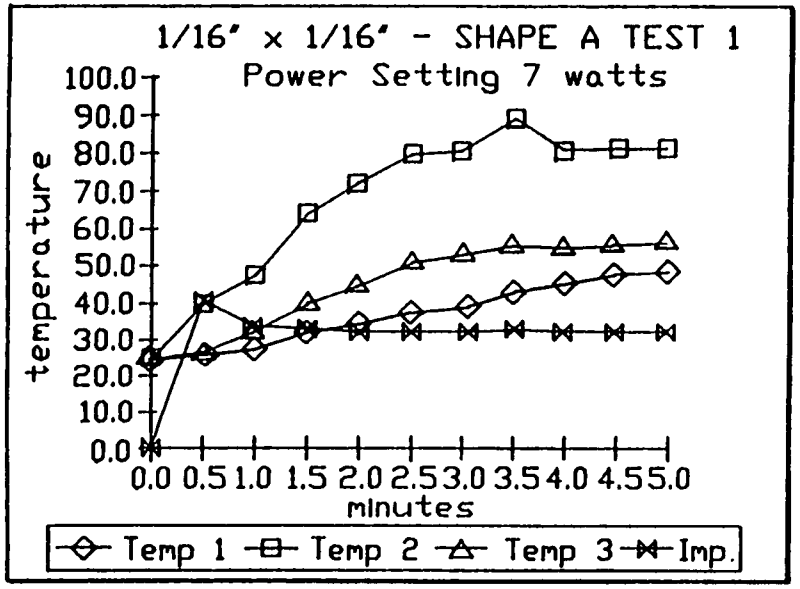


FIG.6(C)

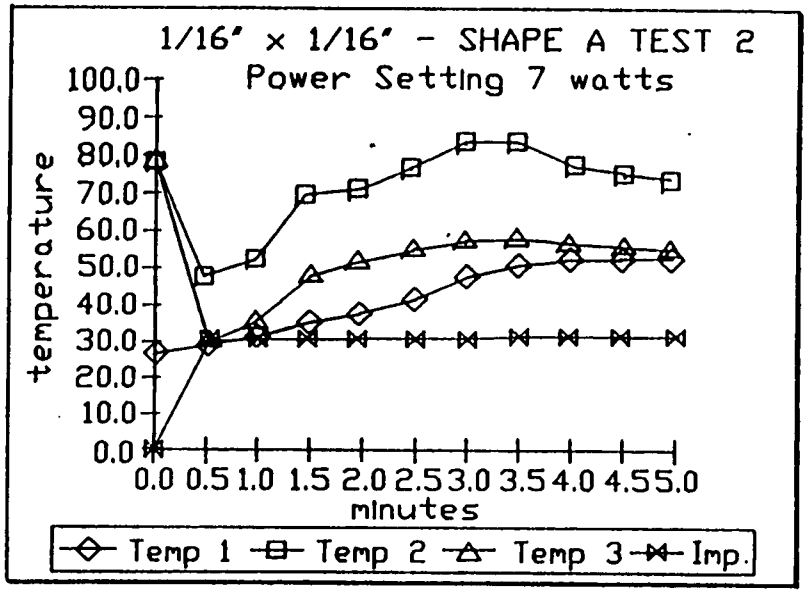
RECTIFIED SHEET (RULE 91)
ISA/EP

FIG.7



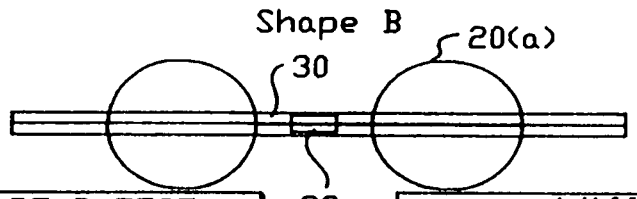


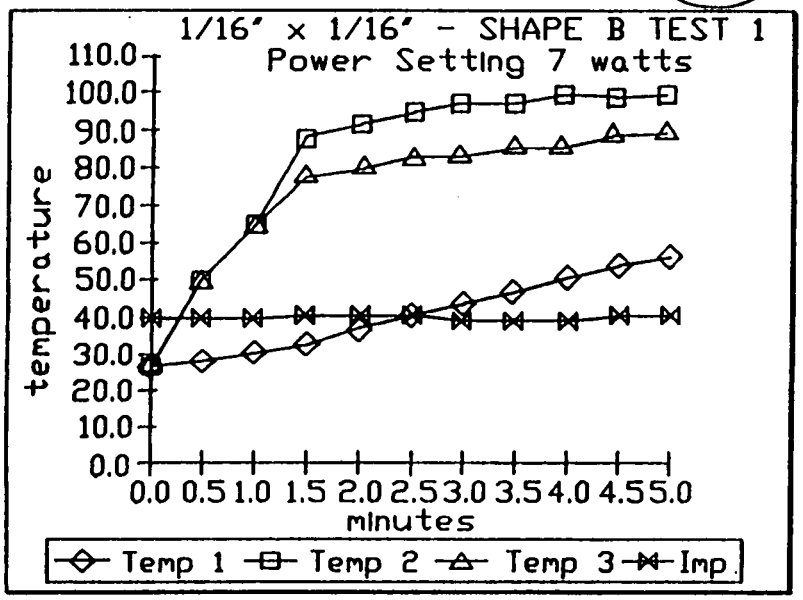
Time	Temp 1	Temp 2	Temp 3	Imp.
0.0	24.4	24.4	24.5	0
0.5	26.0	39.0	27.0	41
1.0	27.0	48.0	32.0	33
1.5	32.0	65.0	41.0	33
2.0	35.0	72.0	46.0	33
2.5	39.0	81.0	51.0	33
3.0	41.3	83.0	53.0	33
3.5	45.0	91.0	57.0	34
4.0	47.0	84.0	56.0	33
4.5	49.0	85.0	57.0	33
5.0	49.0	85.5	58.0	33



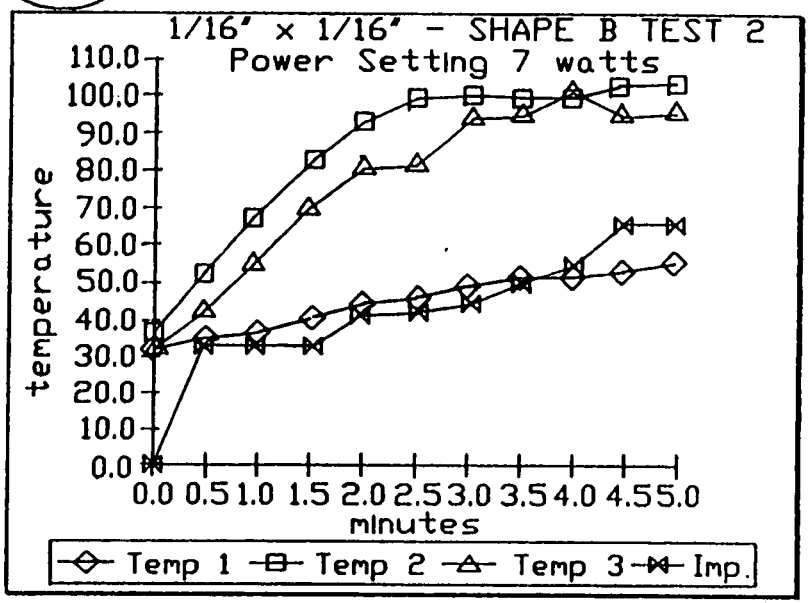
Time	Temp 1	Temp 2	Temp 3	Imp.
0.0	27.0	77.8	77.9	0
0.5	29.0	48.0	30.5	32
1.0	32.0	52.0	36.0	32
1.5	36.0	70.0	48.0	32
2.0	39.0	72.0	52.0	32
2.5	44.0	79.0	56.0	32
3.0	48.0	84.0	58.0	32
3.5	51.0	84.0	58.5	33
4.0	52.0	79.2	56.3	33
4.5	52.2	76.6	55.5	33
5.0	52.1	75.4	54.2	33

FIG.8





Time	Temp 1	Temp 2	Temp 3	Imp.
0.0	27.0	27.3	27.5	40
0.5	29.0	51.0	50.0	40
1.0	31.0	64.8	67.8	40
1.5	34.5	87.0	77.8	41
2.0	38.9	92.8	80.1	41
2.5	43.5	96.5	83.5	41
3.0	46.5	98.1	84.5	39
3.5	49.8	98.2	86.2	39
4.0	52.5	100.0	86.4	39
4.5	54.7	99.7	89.4	41
5.0	56..5	100.1	89.9	41



Time	Temp 1	Temp 2	Temp 3	Imp.
0.0	33.2	37.3	33.1	0
0.5	35.4	52.0	43.0	33
1.0	37.5	68.0	55.0	33
1.5	41.3	84.2	71.2	33
2.0	44.0	93.5	81.0	41
2.5	46.3	98.7	82.5	42
3.0	49.0	99.7	96.2	45
3.5	51.0	99.1	96.7	50
4.0	51.2	99.0	101.7	55
4.5	52.0	101.4	95.0	65
5.0	55.4	102.3	96.5	65

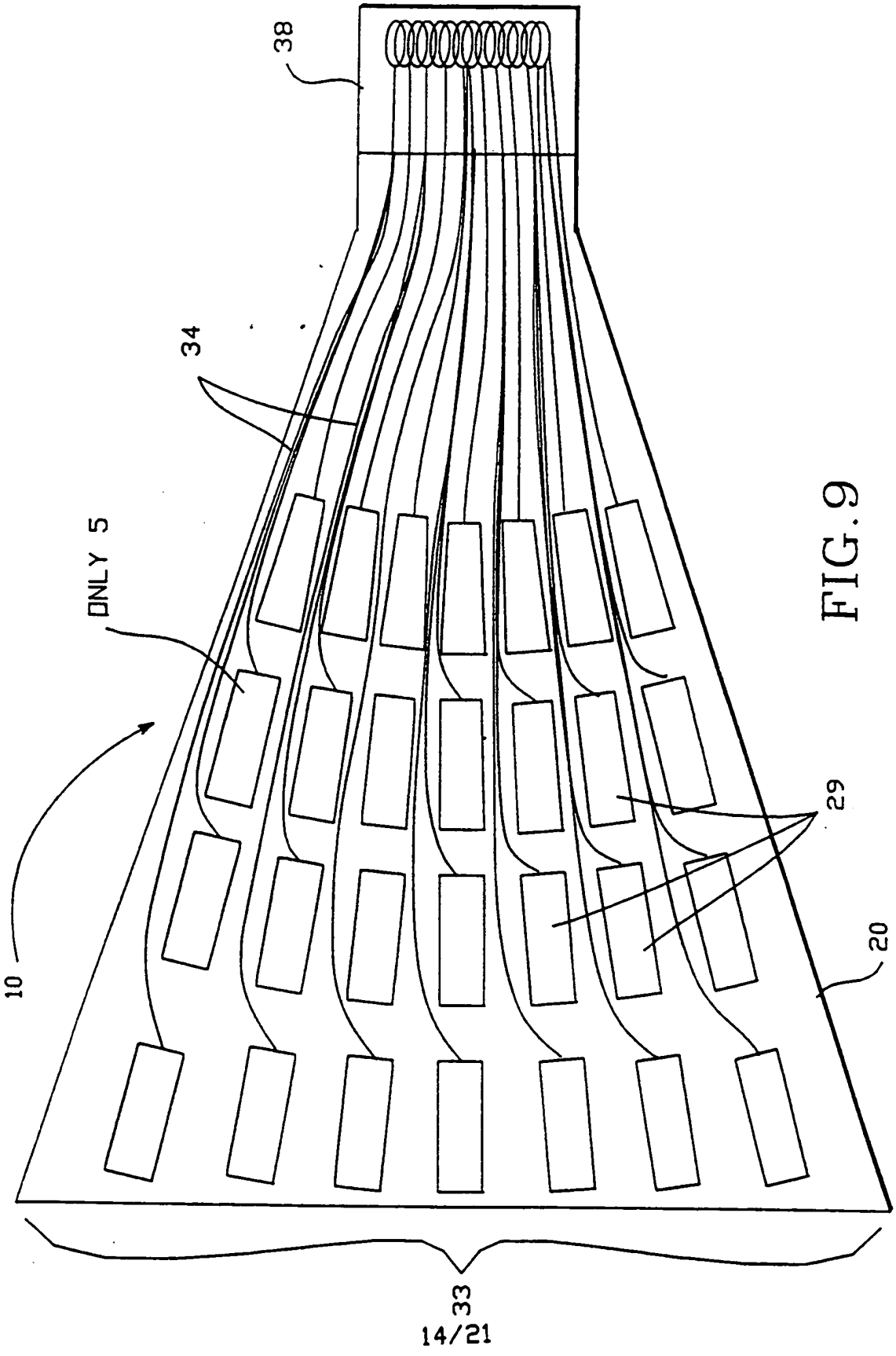


FIG. 9

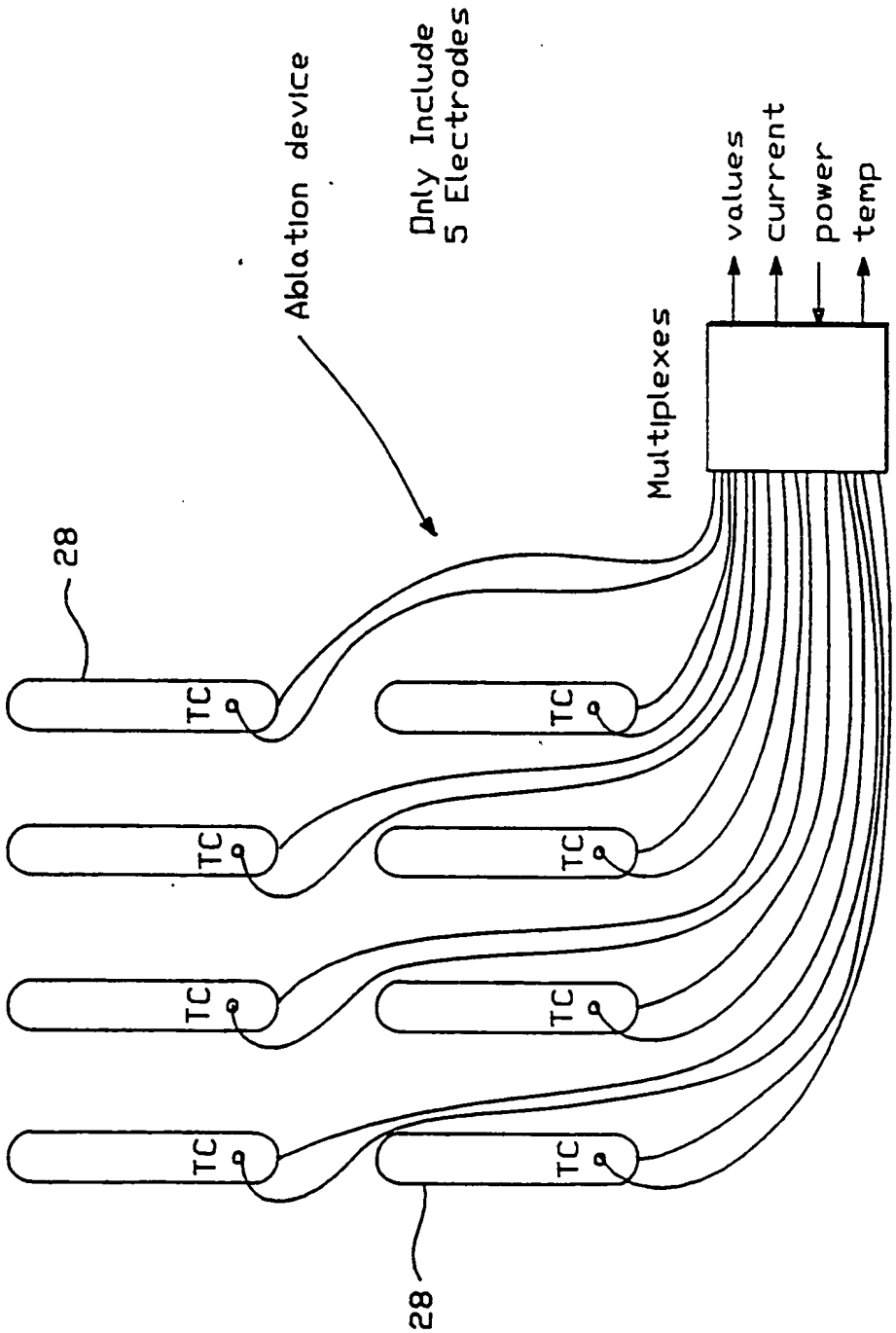

Ablation device
Only Include
5 Electrodes
Multiplexes
values
current
power
temp
28
TC
TC
TC
TC
TC
TC
TC
TC
28

FIG. 10

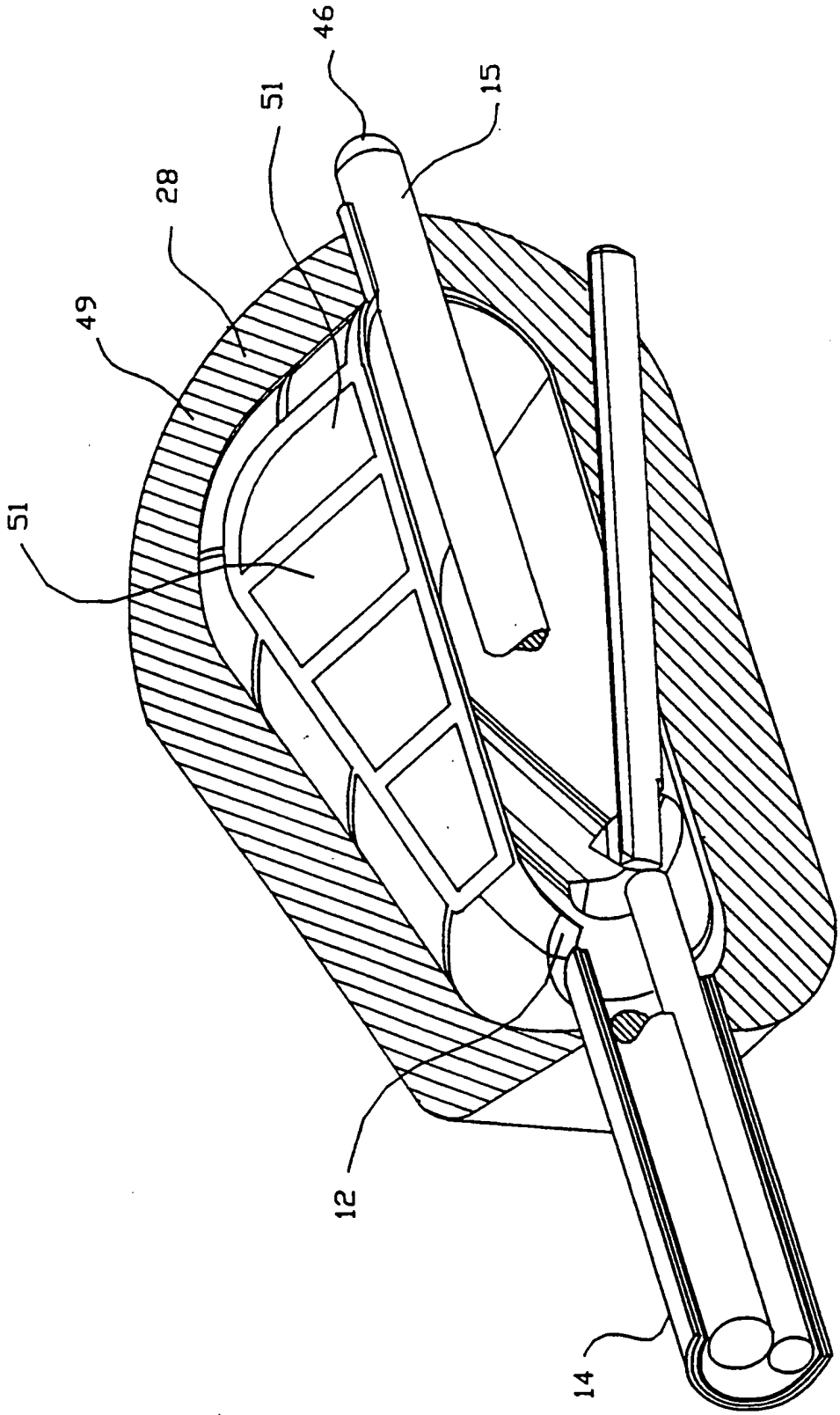


FIG. 11

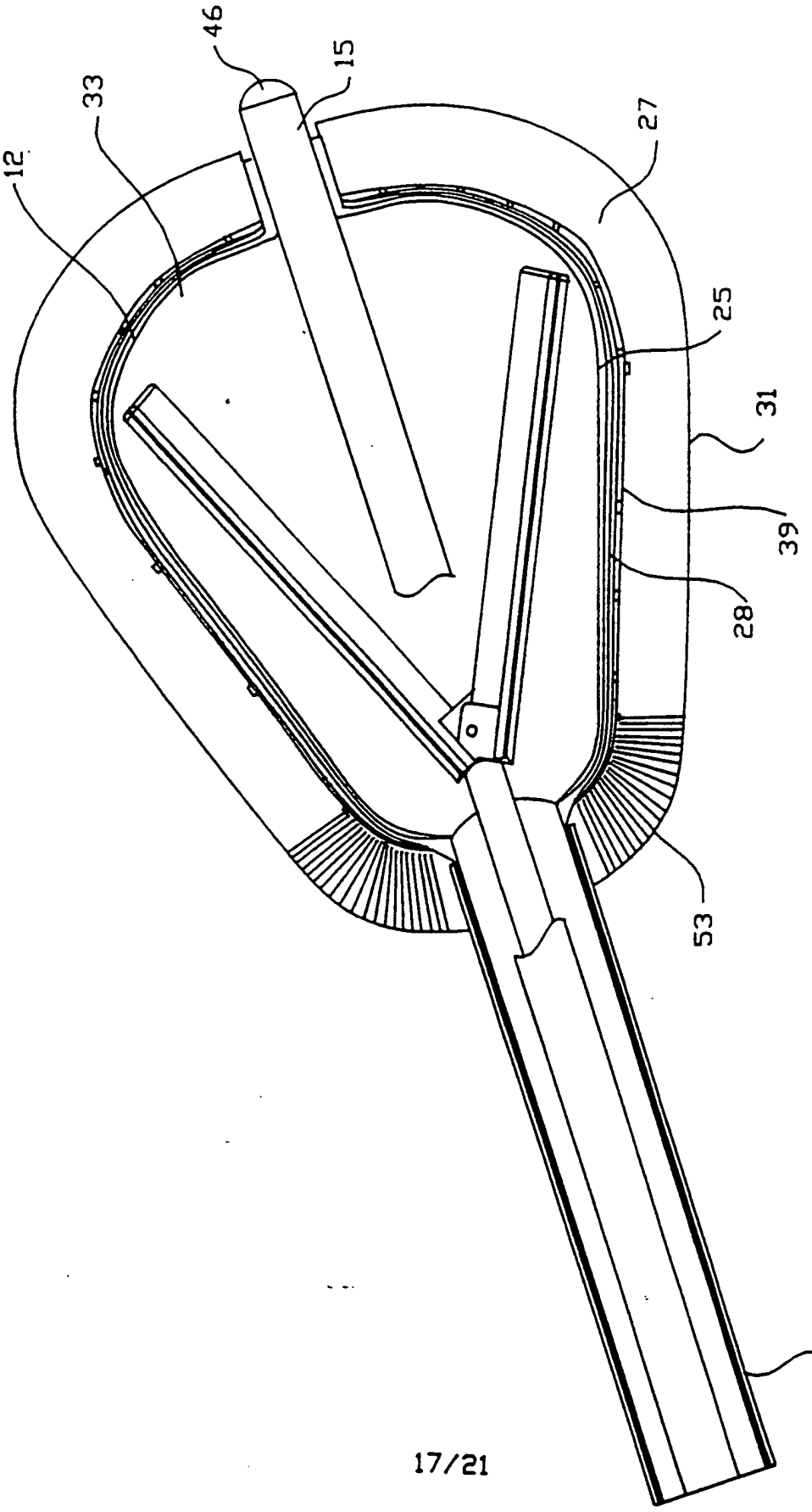


FIG.12

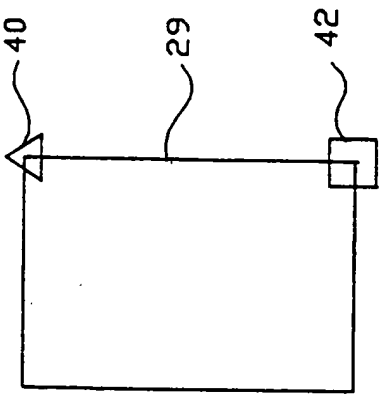


FIG. 13

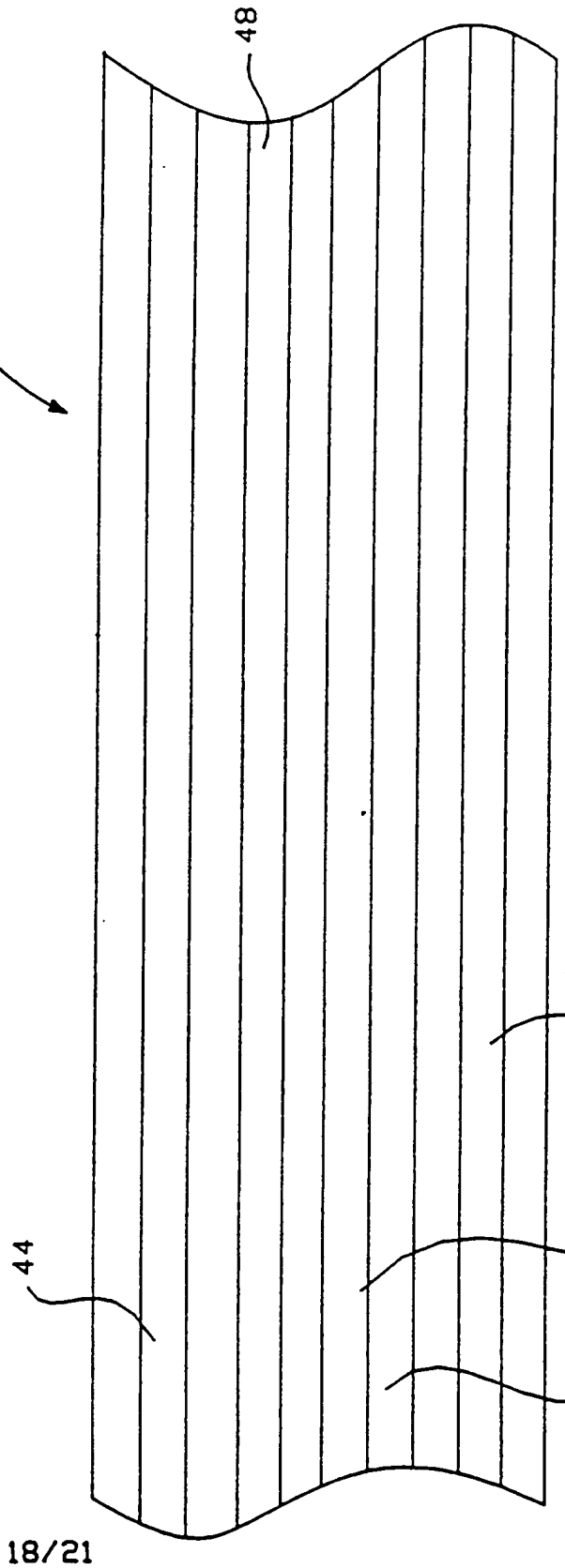


FIG. 14

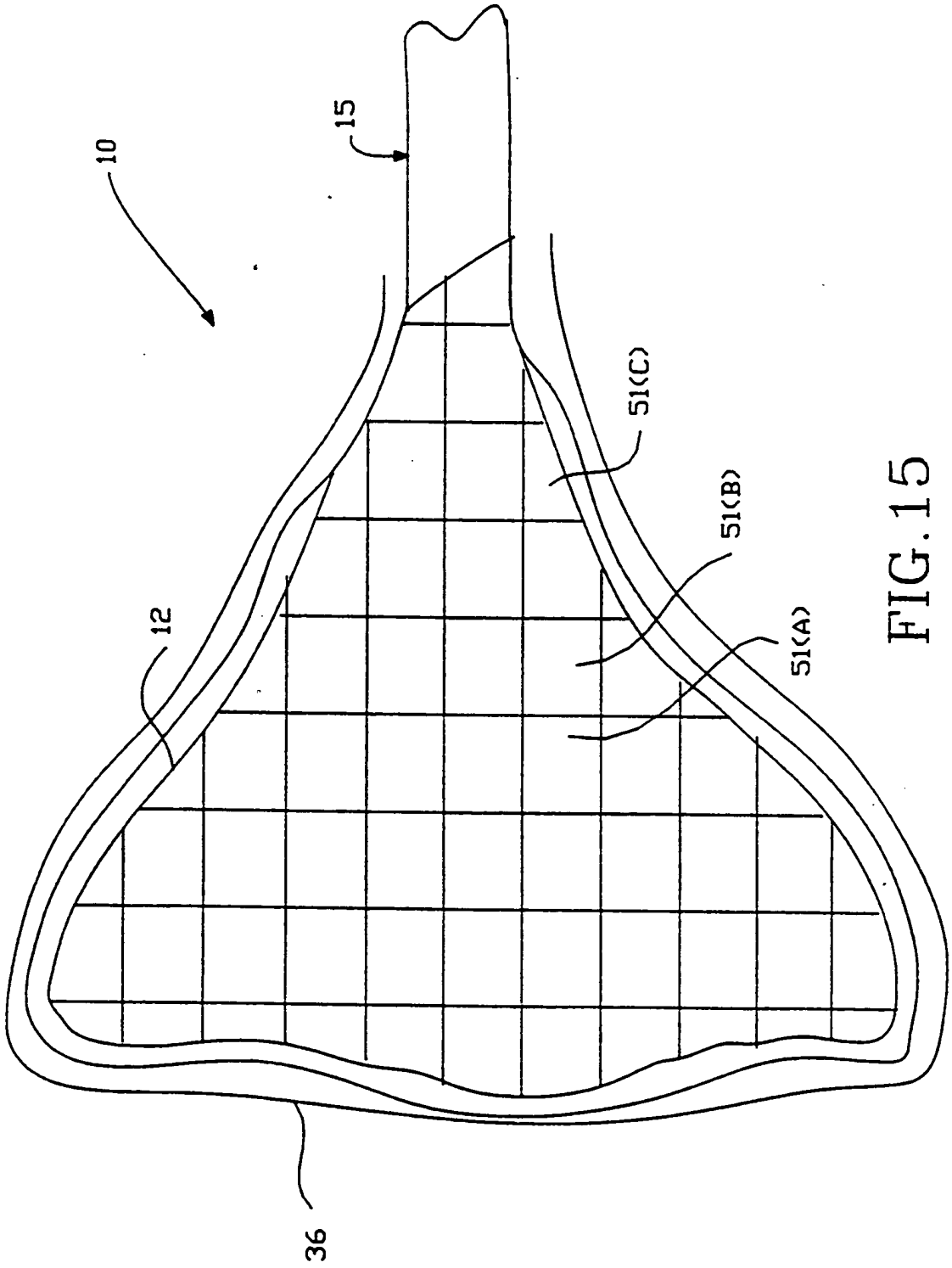


FIG.15

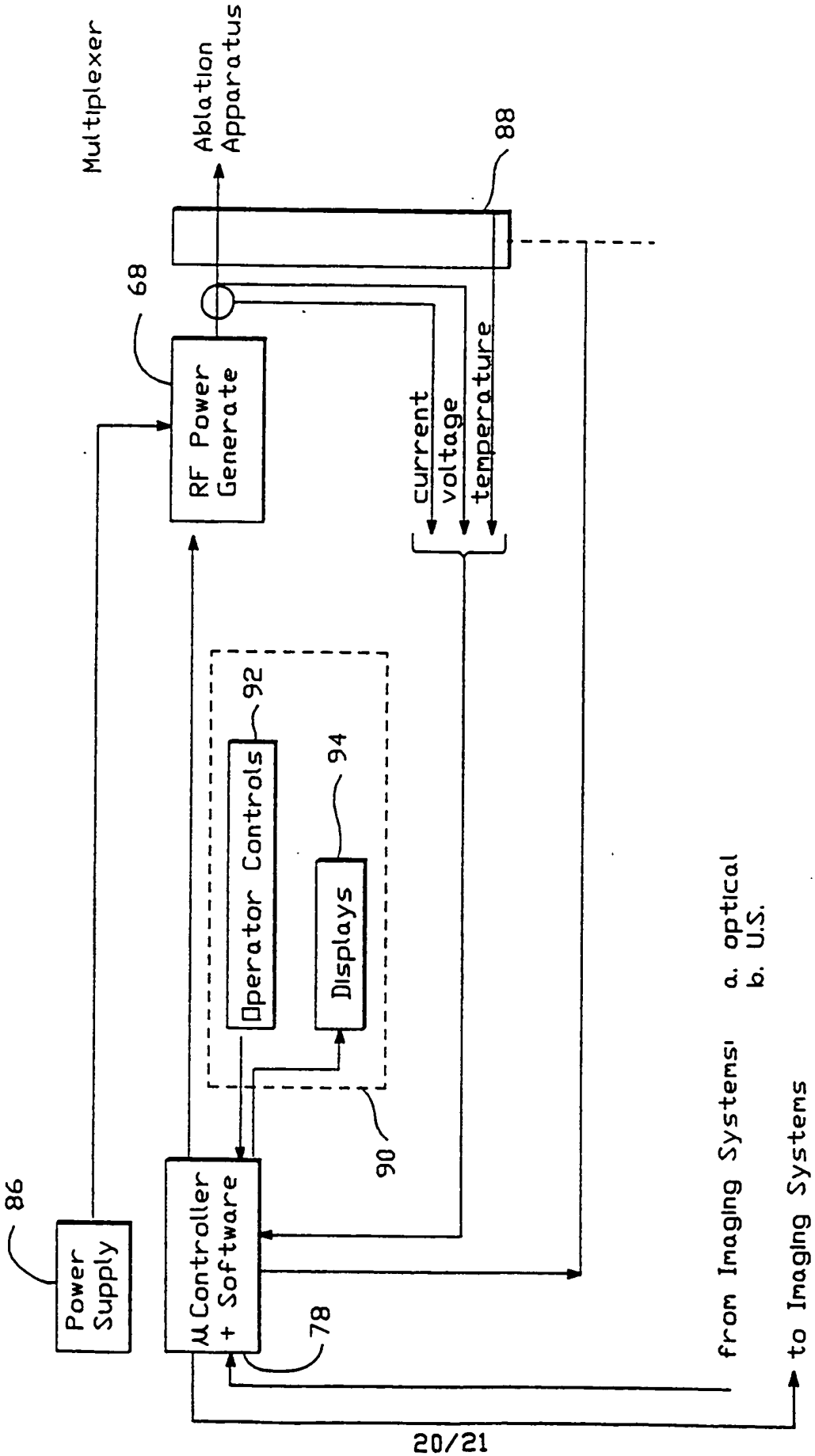

Multiplexer
Ablation Apparatus
88
68
RF Power Generate
current
voltage
temperature
92
Operator Controls
94
Displays
90
86
Power Supply
μ Controller + Software
78
a. optical
b. U.S.
from Imaging Systems
to Imaging Systems
20/21

FIG. 16

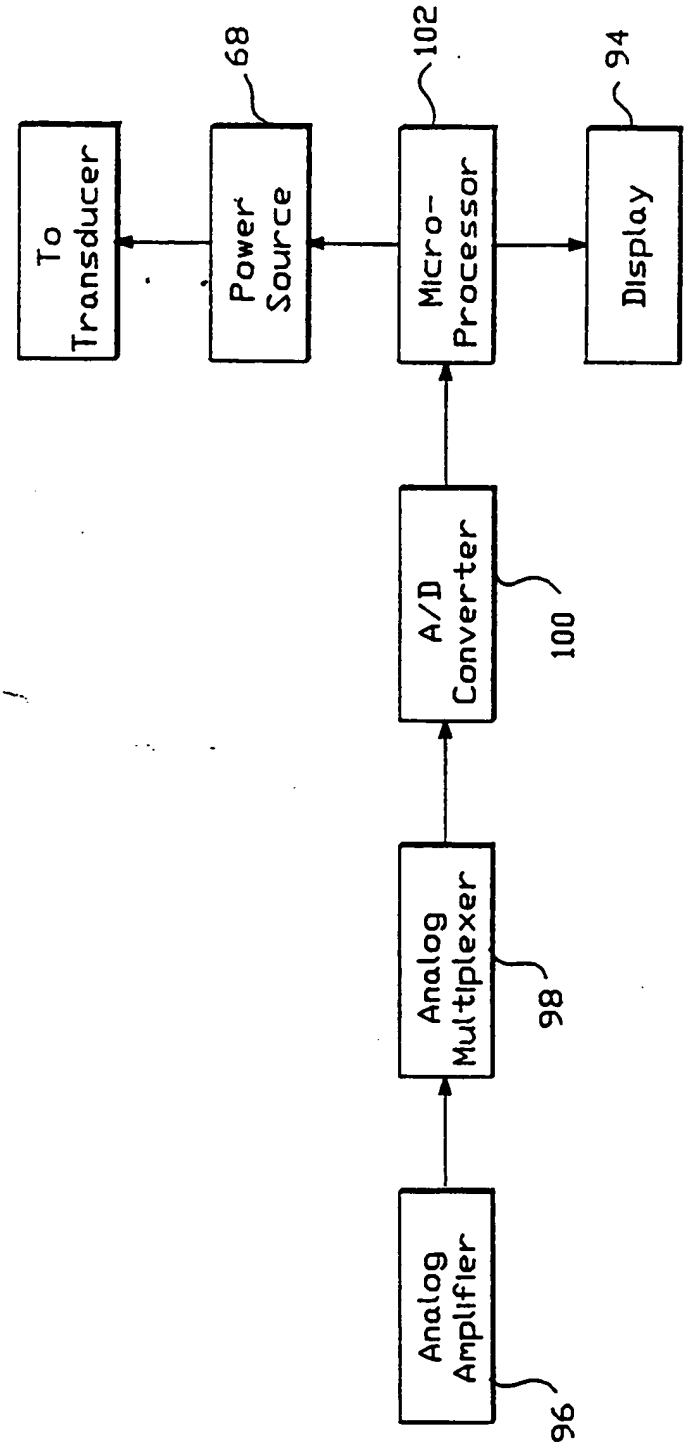

To Transducer
Power Source
68
Micro-Processor
102
Display
94
A/D Converter
100
Analog Multiplexer
98
Analog Amplifier
96

FIG. 17

INTERNATIONAL SEARCH REPORT

Inte: ınal Application No
PCT/US 95/08012

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39 A61N1/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,5 277 201 (STERN) 11 January 1994 cited in the application see the whole document ---	1,19,32

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 October 1995	13. 11. 95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Papone, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter nal Application No
PCT/US 95/08012

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5277201	11-01-94	AU-B-	4105293	29-11-93
		EP-A-	0637943	15-02-95
		FI-A-	945112	31-10-94
		JP-T-	7506033	06-07-95
		NO-A-	944072	26-10-94
		US-A-	5443470	22-08-95
		WO-A-	9321846	11-11-93
		US-A-	5443463	22-08-95